From: Smith, Lem O. [lem.smith@squirepb.com]

Sent: 9/22/2017 12:45:24 AM

To: Jackson, Ryan [jackson.ryan@epa.gov]

Subject: Fwd: Administrator's Internal Meeting Request Form.docx

Attachments: Administrator's Internal Meeting Request Form.docx; ATT00001.htm

Ryan, FYI.

Hope you are doing well.

Best, Lem

Sent from my Verizon, Samsung Galaxy smartphone

----- Original message -----

From: "Newberry, Edward" <edward.newberry@squirepb.com>

Date: 9/21/17 6:35 PM (GMT-07:00)

To: hupp.millan@epa.gov

Cc: "Smith, Lem O." <lem.smith@squirepb.com>, "Winters, Karen A." <karen.winters@squirepb.com>

Subject: Administrator's Internal Meeting Request Form.docx

Millan,

Per our discussion. Lem Smith is also reaching out to Ryan about this. Thanks for your help!

Ed

Edward J. Newberry Global Managing Partner Squire Patton Boggs LLP 2550 M Street, NW Washington, DC 20037



46 Offices in 21 Countries

This message is confidential and may be legally privileged or otherwise protected from disclosure. If you are not the intended recipient, please telephone or email the sender and delete this message and any attachment from your system; you must not copy or disclose the contents of this message or any attachment to any other person.

Squire Patton Boggs (US) LLP is part of the international legal practice Squire Patton Boggs, which operates worldwide through a number of separate legal entities. Please visit www.squirepattonboggs.com for more information.				
JS				



Meeting Request Form for Administrator Scott Pruitt

Today's Date: 9/21/17

Requesting Office: Office of the Administrator

Title of the Meeting: Formaldehyde Manufacturers

Purpose: Discuss IRIS Assessment of Formaldehyde

Role of the Administrator: Provide direction to ORD/NCEA/IRIS

Background: In 2012, the National Academy of Sciences issued a harshly critical peer review of the previous draft of the IRIS assessment of formaldehyde, making significant recommendations for improvements for that review and for the overall IRIS program. The revised IRIS assessment must reflect a thorough and objective review of all the relevant scientific data.

Last possible date for the meeting: Meeting before any action is taken regarding formaldehyde recommendations.

Is the meeting urgent and if so why?: Yes, the draft is ready for internal agency review and comment.

Requested Time Length: 30 minutes

EPA Staff (Required): No

EPA Staff (Optional): At EPA discretion, Samantha Dravis, Richard Yamada

External Participants: Ed Newberry, Squire Patton Boggs, the CEOs and/or the COOs of Hexion, Celanese and Georgia Pacific and other representatives of these companies, and Cal Dooley, American Chemistry Council.

Teleconference Required?: No

Video Conference Required?: (If so please provide the conference room name to be used for video connection) No

Point of Contact for the Meeting: Edward J. Newberry, Partner, Squire Patton Boggs (US) LLP: edward.newberry@squirepb.com, Ex. 6

NOTE: Meeting request forms should be submitted to [HYPERLINK "mailto:scheduling@epa.gov"], with a copy to Aaron Dickerson at [HYPERLINK "mailto:dickerson.aaron@epa.gov"], and the AO Special Assistant who covers your office. All briefing material must be sent to your AO Special Assistant by 3:00 pm two days before your meeting, or to OCIR 48 hours in advance. If briefing materials are not submitted on time, we may need to reschedule your briefing.

From: Annie Snider [asnider@politico.com]

Sent: 7/5/2018 4:29:54 PM

To: Jackson, Ryan [jackson.ryan@epa.gov]

Subject: Politico inquiry: formaldehyde assessment

Ryan -- Annie Snider from Politico here. I've been in touch with your press shop (statement from them below) but wanted to personally give you a heads up & chance to weigh in on a story we're running later today or tomorrow morning about the IRIS formaldehyde assessment.

I've got 2 sources – a current & a former career official – who say politicals, including you, are "stonewalling" the assessment, keeping it from going through internal review processes and thus being made public. They laid out several scenarios where key briefings for the air office were cancelled, and said pains were taken to keep things from being put in writing. They say the assessment has been complete since last fall, and at a January EPW hearing Administrator Pruitt said that it was his understanding that the assessment was complete. The sources say the assessment finds health risks, including leukemia, at very low levels of exposure that most Americans are exposed to thru daily life. They also said that other IRIS assessments are being slow-walked or undermined.

Here's what your press shop got me:

"EPA continues to discuss this assessment with our Agency program partners and have no further updates to provide at this time. Assessments of this type are often the result of needs for particular rulemakings and undergo an extensive intra-agency and interagency process. Mr. Yamada and Mr. Jackson have not cancelled briefings on assessments or during the IRIS process, and in fact have requested briefings. The National Academy of Science and Congress in legislative reports have for years been highly critical of EPA's previous assessments involving formaldehyde." - EPA Spokesperson

On background:

Nancy Beck is the Deputy Assistant Administrator for the Office of Chemical Safety and Pollution Prevention. She does not lead, direct, or make decisions for the IRIS program, which is in the Office of Research and Development.

Let me know if you want to weigh in. Thanks --

Annie Snider
Reporter
POLITICO
asnider@politico.com
Ex. 6

@AnnElizabeth18

From: D'Amico, Louis [DAmico.Louis@epa.gov]

Sent: 5/12/2016 10:07:32 PM

To: Ross, Mary [Ross.Mary@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]; Bussard, David

[Bussard.David@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]; Kraft, Andrew

[Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]

Subject: Edits to ACC response?

Attachments: ACC Draft Letter on NAS Recommendations for Formaldehyde - Final 04 13 1....pdf; ACC FA Response -

BurkeKadeli_draft1.docx

Hi everyone,

Attached is first draft of a response to ACC (that will ultimately come from the IOAA) regarding the formaldehyde

assessment. David,

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks all!

-Lou

Louis D'Amico, Ph.D.

Acting Communications Director

National Center for Environmental Assessment | U.S. EPA - Office of Research and Development

Mail Code 8601P | 1200 Pennsylvania Ave, NW | Washington, DC 20460

Physical/Overnight Delivery Address: U.S. EPA | Two Potomac Yard (North Building), N-7651 | 2733 S. Crystal Drive | Arlington, VA

22202

Office: 703-347-0344 | Mobile

Personal Matters / Ex. 6

Fax: 703-347-8689 | email: damico.louis@epa.gov

From: Kraft, Andrew [Kraft.Andrew@epa.gov]

Sent: 4/26/2016 3:09:56 PM

To: Bussard, David [Bussard.David@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]

CC: Glenn, Barbara [Glenn.Barbara@epa.gov]; Perovich, Gina [Perovich.Gina@epa.gov]; Hagerthey, Scot

[Hagerthey.Scot@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Cogliano, Vincent [cogliano.vincent@epa.gov]

Subject: RE: updated draft slides for Kavlock briefing

Attachments: Kavlock_Apr2016_bckgrnd.docx; HCHOBriefKavlock042816.pptx

Hi David,

We decided to cut a couple slides, and added some minimal text. Please find the updated slides and background materials attached.

-Barbara and Andrew

From: Bussard, David

Sent: Tuesday, April 26, 2016 10:28 AM

To: Kraft, Andrew < Kraft. Andrew@epa.gov>; Birchfield, Norman < Birchfield. Norman@epa.gov>

Cc: Glenn, Barbara <Glenn.Barbara@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; Hagerthey, Scot

<Hagerthey.Scot@epa.gov>

Subject: RE: updated draft slides for Kavlock briefing

Barbara and Andrew,

Vince told me he is okay with the slides.

If you have any other changes, let he and I know asap, so that he does not send the wrong version. He plans to send to Kavlock by 2 pm today.

Deliberative Process / Ex. 5

David

From: Kraft, Andrew

Sent: Monday, April 25, 2016 5:09 PM

To: Bussard, David <<u>Bussard.David@epa.gov</u>>; Birchfield, Norman <<u>Birchfield.Norman@epa.gov</u>>; Perovich, Gina

<Perovich.Gina@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>

Cc: Glenn, Barbara < Glenn.Barbara@epa.gov >

Subject: RE: updated draft slides for Kavlock briefing

Thank you, David.

Please see the attached draft background materials for Bob K.

Barbara and Andrew

From: Bussard, David

Sent: Monday, April 25, 2016 4:28 PM

To: Kraft, Andrew < Kraft. Andrew@epa.gov >; Birchfield, Norman < Birchfield. Norman@epa.gov >; Perovich, Gina

<Perovich.Gina@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>

Cc: Glenn, Barbara < Glenn.Barbara@epa.gov>

Subject: RE: updated draft slides for Kavlock briefing

Barbara and Andrew,

I like the revisions.

It is still potentially a lot to cover, but I think if you are clear what you want to cover if you are short on time and what you can cover if there is more time or Bob K wants to pursue a point, I think this can work.

David

From: Kraft, Andrew

Sent: Monday, April 25, 2016 4:12 PM

To: Bussard, David <Bussard.David@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; Perovich, Gina

<Perovich.Gina@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>

Cc: Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>

Subject: updated draft slides for Kavlock briefing

Hi all,

Please see the attached revised slide deck for the Kavlock briefing this Thursday and let us know if you have any comments.

Deliberative Process / Ex. 5

Thanks!

-Barbara and Andrew

From: Itkin, Cheryl [Itkin.Cheryl@epa.gov]

Sent: 9/22/2016 4:46:10 PM

To: Bussard, David [Bussard.David@epa.gov]; Hagerthey, Scot [Hagerthey.Scot@epa.gov]

CC: Birchfield, Norman [Birchfield.Norman@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara

[Glenn.Barbara@epa.gov]; D'Amico, Louis [DAmico.Louis@epa.gov]

Subject: RE: Formaldehyde on the Public Peer Review Agenda

David - thank you, that sounds good. I'll use the wording you provided.

For now, I am providing a note and my checklist to disperse some of the mystery about the EPA Peer Review Agenda (PRA) – I think this may shed some light on your questions and provide some answers. I'll revisit your questions soon but I thought this may be good for now.

All federal agencies are required to "post on their Web sites a **Peer Review Agenda that includes all planned and ongoing** influential scientific information subject to the Bulletin's peer review requirements." The EPA Peer Review Agenda (PRA), https://cfpub.epa.gov/si/si_public_pr_agenda.cfm, has a main listing of influential products that includes those planned (approaching peer review in the next year) and ongoing (currently in the peer review cycle).

What are the endpoints for the peer review cycle? EPA's peer review cycle for an influential product begins with the Peer Review Plan and ends with the Agency Response. While OMB considers the peer review complete when the final peer review report is done, EPA considers peer review complete when the Agency Response to the peer review report is done. So, each product stays on the PRA main listing until the Agency Response is posted or reported or noted in the Science Inventory record. Within 30 days of completing the record on the PRA, the system automatically moves it to the PRA "archive" section called Influential Products with Completed Peer Reviews. You can access the archive section by going to the box in the right margin of the site and scrolling to the bottom of the list of Annual Peer Review Reports (to OMB) or you can go direct to (https://cfpub.epa.gov/si/si public pr agenda archive.cfm). Feel free to look up older completed peer reviews.

For each product, every step in the peer review cycle is documented on the peer review agenda. I update along the way (well, I should be), it's more likely that I perform the update twice a year - doing catchup. Typically, I link to what the SAB and Maureen post online. It is a tedious process to collect info, tag, enter metadata and link or load these items but it is required by the agency and OMB.

I'm sharing **my checklist** below. It is based on established milestones that trigger what I need to do and when I need to do it – these are my steps for updating the Science Inventory and publishing the info through the Peer Review Agenda website at https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

Step 0: What triggers starting the peer review cycle and getting into the queue for the Peer Review Agenda?

- Annual Data Call from OSA to update the PRA around October, seems to get earlier each year
- -(IRIS Step 4a) the public comment ERD is released. If missed, then post within 3 to 6 months prior to the panel meeting.
 - SCOUT or equivalent tracking system
 - someone alerts me that a HISA or ISI draft product (ie. ISA, HF, etc...) will be completed and released soon
 - Annual Call for Nominations to the SAB if not already alerted from other triggers

<u>Step 1</u>: - **A) Approve Peer Review Decision Summary Memo** (internal documentation template available online, completed by the project lead and signed by the Division Director, Peer Review Coordinator, and Center Director).

- B) Establish Science Inventory Record (coordinate with Maureen and Marieka) and create placeholder on Peer Review Agenda (PRA plan is under development, gather info and get approvals)

Step 2: Post Public Peer Review Plan on PRA with 30-day public comment period on the peer review plan (includes completing part 1 of OMB questions)

Step 3: ERD and Charge are Posted online by SAB or NCEA Webmaster, may be announced in a FRN: Link and enter metadata for Peer Review Charge and ERD

Step 4: **Peer Review Panel Meeting Date is Announced in a FRN**: Enter Actual date of Peer Review Panel Meeting in key SI date field

<u>Step 5</u>: **Peer Review Report is posted online by SAB or NCEA Webmaster**: Link and enter metadata for Peer Review Report, (complete key SI date fields), Collect info from the Peer Review Leader or DFO (complete part 2 of OMB questions)

Step 6: Agency Response is posted online by SAB or NCEA Webmaster: Link and enter metadata for Agency Response to the Peer Review Report. If no formal response is posted or incorporated in a final product, or if the Agency decides to revise the product and submit the product for another round of peer review > create a note and post to complete the peer review cycle for the ERD that was peer reviewed. Peer review for that iteration of the product is considered complete.

Does this help?

Cheryl

From: Bussard, David

Sent: Thursday, September 22, 2016 8:26 AM

To: Itkin, Cheryl < Itkin. Cheryl@epa.gov>; Hagerthey, Scot < Hagerthey. Scot@epa.gov>

Cc: Birchfield, Norman <Birchfield.Norman@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara

<Glenn.Barbara@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>

Subject: FW: Formaldehyde on the Public Peer Review Agenda

Deliberative Process / Ex. 5

David

PS: Some communication points generally: Not urgent, but a record of what I found when looking for the IRIS Formaldehyde "landing page".

More than you want to deal with right now, NCEA may want to think about this broadly at some point. I believe Maureen Johnson has talked about "landing pages" for each chemical.

I see there is an EPA page on "formaldehyde", that currently does not have anything about IRIS: https://www.epa.gov/formaldehyde, but has a page on toxicity on which one can find a link titled "Status of IRIS toxicological review of formaldehyde (inhalation) EPA is currently revising its IRIS assessment of formaldehyde to address the 2011 National Academy of Sciences peer review recommendations. This assessment addresses both noncancer and cancer human health effects that are relevant to assessing the risks from chronic inhalation exposure to formaldehyde. When finalized, the updated toxicological profile for formaldehyde will appear in the IRIS database."

That in turn goes to a webpage that I'd prefer had a different title. It's current title is "IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft

2010)". https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614

And, on that, if I clikc on "IRIS CHEMICAL PAGE" I can find a page that is labeled "Landing Page", https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=419, that has as status: Status: Formaldehyde is in step 4 at this time; see Quick Check." It in turn looks like it should be a link, but if so, it does not seem to lead anywhere.

David

From: Itkin, Cheryl

Sent: Wednesday, September 21, 2016 5:56 PM

To: Bussard, David <Bussard.David@epa.gov>; Hagerthey, Scot <Hagerthey.Scot@epa.gov>

Subject: Formaldehyde on the Public Peer Review Agenda

Hi David and Scot,

I need 2 minutes of your time. I'm cleaning up the Science Inventory/Peer Review Agenda website. OSA and OMB are the main audience and the public may monitor this site as well. The peer review information for the **Formaldehyde assessment (2010)** still appears on the Agency's public peer review agenda website. I'd like to closeout the record so it disappears from the Peer Review Agenda website to make way for the next formaldehyde peer review but the system requires me to make a statement or link to an **Agency response** to the peer review that occurred.

Please let me know if its ok for me to enter this simple statement:

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5 pr if you want me to redirect by linking to a document already on the web.

Here is how it currently appears on the list online at https://cfpub.epa.gov/si/si_public_pr_agenda.cfm

Office of Research and Development

Products

- IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010) (IRIS ASSESSMENT)

If you click on the title or go direct to https://cfpub.epa.gov/si/si_public_pra_view.cfm?dirEntryID=223614 you see this (the last update years ago was the link added to the NAS report at nap.edu):

The draft Toxicological Review of Formaldehyde-Inhalation Assessment provides scientific support and rationale for the hazard and dose-response assessment pertaining to chronic inhalation exposure to formaldehyde.

Contact: Technical Information Staff (703) 347-8561, nceadc.comment@epa.gov

Office: OFFICE OF RESEARCH AND DEVELOPMENT

Full Record ID: 223514

You may choose to be added or removed from the document change notification list:

September 1997 State of the Se

rot.		•	Public Comment Period
File	Type	Version	Begin End
PEER REVIEW PLAN 223614 PDF (Com. 300 Annual 2020)	Peer Review Plan	1	not available for comment
FORMALDEN'DE - CHARGE TO THE NAS PANEL POE 12 = 244 About 920	Peer Review Charge	1	not available for comment
NAS-FINAL-REPORTATION	Peer Review Report	1	not available for comment
IRIS FORMALDERYDE FRO 61710.PDF (1040 psi 7525K 865/4.800)	Product		not available for comment

Thanks, Cheryl

From: D'Amico, Louis [DAmico.Louis@epa.gov]

Sent: 5/11/2016 6:45:06 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]

Subject: FYI. Latest ACC letter on FA

Attachments: ACC Draft Letter on NAS Recommendations for Formaldehyde - Final 04 13 1....pdf

Attached.

Louis D'Amico, Ph.D.

Acting Communications Director

National Center for Environmental Assessment | U.S. EPA - Office of Research and Development

Mail Code 8601P | 1200 Pennsylvania Ave, NW | Washington, DC 20460

Physical/Overnight Delivery Address: U.S. EPA | Two Potomac Yard (North Building), N-7651 | 2733 S. Crystal Drive | Arlington, VA

22202

Office: 703-347-0344 | Mobile | Personal Matters / Ex. 6 | Fax: 703-347-8689 | email: damico.louis@epa.gov

From: Kopylev, Leonid [Kopylev.Leonid@epa.gov]

Sent: 6/9/2016 7:03:51 PM

To: Glenn, Barbara [Glenn.Barbara@epa.gov]

CC: Kraft, Andrew [Kraft.Andrew@epa.gov]; Morozov, Viktor [Morozov.Viktor@epa.gov]; Jones, Samantha

[Jones.Samantha@epa.gov]

Subject: marginal comments main text (RFc)

Attachments: Formaldehyde draft Tox Review ERC May2016.lk.docx

Barbara,

Deliberative Process / Ex. 5

Hope this helps and please let me know if any of my comments are unclear.

Thanks,

Leonid

From: Glenn, Barbara

Sent: Thursday, June 09, 2016 2:11 PM

To: Kopylev, Leonid < Kopylev.Leonid@epa.gov>; Bateson, Thomas < Bateson.Thomas@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov>; Morozov, Viktor < Morozov. Viktor@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>

Subject: RE: intermediate report on non-cancer formaldehyde analyses and also comment on study tables

Hi Leonid,

Thank you very much. We appreciate your careful feedback.

-Barbara

From: Kopylev, Leonid

Sent: Thursday, June 09, 2016 11:20 AM

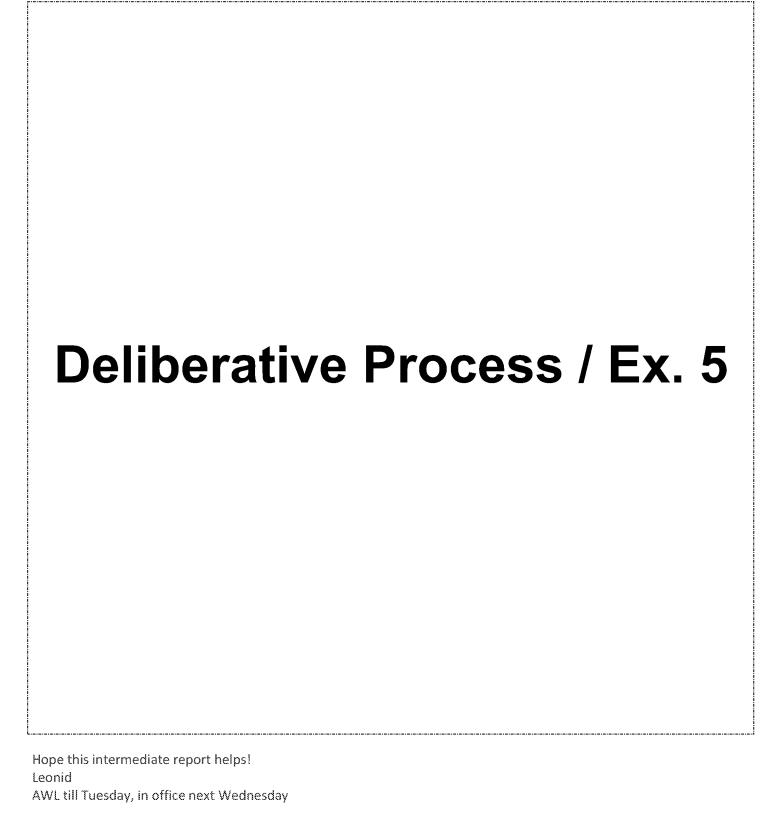
To: Bateson, Thomas < Bateson. Thomas@epa.gov >; Glenn, Barbara < Glenn. Barbara@epa.gov >

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov>; Morozov, Viktor < Morozov, Viktor@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>

Subject: intermediate report on non-cancer formaldehyde analyses and also comment on study tables

Tom:



From: Glenn, Barbara

Sent: Friday, June 03, 2016 2:45 PM

To: Jones, Samantha < Jones. Samantha@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov>; Hogan, Karen < Hogan. Karen@epa.gov>; Kopylev, Leonid

<Kopylev.Leonid@epa.gov>

Subject: Documentation for derivation of BMC and BMCL for formaldehyde noncancer endpoints

Deliberative Process / Ex. 5

Thank you for reviewing formaldehyde!

Barbara and Andrew

From: Bussard, David [Bussard.David@epa.gov]

Sent: 9/14/2016 5:50:21 PM

To: Birchfield, Norman [Birchfield.Norman@epa.gov]

CC: Jones, Samantha [Jones.Samantha@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara

[Glenn.Barbara@epa.gov]

Subject: FW: IRIS assessment for formaldehyde

Attachments: Formaldehyde and Paraformaldehyde PWP 9-14-16.docx

Norm,

I spoke with Mike Slimak and Ted Berner.

Mike would like us to limit our time investment, but he is okay with our giving it a quick read.

Deliberative Process / Ex. 5

Let me know if other issues arise with a quick read that you, Barbara or Andrew think we should point out.

David

From: Bussard, David

Sent: Wednesday, September 14, 2016 9:49 AM

To: Kraft, Andrew < Kraft. Andrew@epa.gov>; Glenn, Barbara < Glenn. Barbara@epa.gov>; Birchfield, Norman

<Birchfield.Norman@epa.gov>

Cc: Jones, Samantha < Jones. Samantha@epa.gov>; Ross, Mary < Ross. Mary@epa.gov>

Subject: FW: IRIS assessment for formaldehyde

Barbara, Andrew and Norm,

Please carefully review their discussion of IRIS, and their timeline. Are their statements about utilizing IRIS consistent with a realistic timeline for a final assessment?

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

David

From: ONeill, Sandra

Sent: Wednesday, September 14, 2016 8:33 AM

To: Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Bussard, David

<Bussard.David@epa.gov>

Cc: Gayoso, Jose < Gayoso Jose@epa.gov > **Subject:** FW: IRIS assessment for formaldehyde

Andrew, et al.,

AD is nearing completion of the Formaldehyde and Paraformaldehyde Preliminary Work Plan. Our goal is to complete this workplan by the end of next week. We mention that we will include the IRIS review and determine whether new endpoints would be selected, incorporating this into our registration review. I've attached a draft of the document, can you let me know if you have any comments by next Tuesday, March 20? And also, if you have any questions on the document.

Thanks in advance.

Sincerely,

Sandra O'Neill Chemical Review Manager OCSPP/OPP/AD 703 347 0141

From: Kraft, Andrew

Sent: Tuesday, August 16, 2016 4:39 PM **To:** ONeill, Sandra < ONeill.Sandra@epa.gov>

Cc: McMahon, Tim < McMahon. Tim@epa.gov>; Glenn, Barbara < Glenn. Barbara@epa.gov>; Birchfield, Norman

<Birchfield.Norman@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>

Subject: RE: IRIS assessment for formaldehyde

Hi Sandra,

Yes, Barbara and I are working on the IRIS formaldehyde assessment (we are the assessment managers). We do not currently have a publically available, up-to-date schedule for release of the document for peer review, nor for finalization after peer review. Thus, we do not have a date that could be released through your workplan.

Note that prior to release of the assessment for peer review (which can take up to several years to complete, depending on the peer review mechanism), we still have to complete internal EPA clearance of the document, Interagency review by federal partners, and release of the assessment for comments from the general public.

Barbara, myself, and/ or Norm (our branch chief) can address any questions you may have, and, internally, we can provide you with more details on the assessment's progress.

Best,

From: ONeill, Sandra

Sent: Tuesday, August 16, 2016 3:38 PM

To: Kraft, Andrew < Kraft. Andrew@epa.gov >
Cc: McMahon, Tim < McMahon. Tim@epa.gov >
Subject: IRIS assessment for formaldehyde

Hi Andrew,

I'm AD's CRM working on the formaldehyde and paraformaldehyde registration review case. We're publishing a Preliminary Work Plan for this case by the end of September and also providing a brief presentation to OPP's front office at the end of this month on this case. I understand you're working on the IRIS assessment? Do you have a timeline in place for when the peer review might be completed, or know who I might contact for this information?

Thanks very much,

Sandra O'Neill

Chemical Review Manager

Regulatory Management Branch 2 II Antimicrobials Division II OPP/OCSPP II U.S. EPA II (703) 347-0141

From: Bussard, David [Bussard.David@epa.gov]

Sent: 5/11/2016 6:40:34 PM

To: Glenn, Barbara [Glenn.Barbara@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Birchfield, Norman

[Birchfield.Norman@epa.gov]

Subject: FA discussion of uncertainty

Attachments: DBcmts(ver4) on FormaldehydeTRdraft050616.docx

Deliberative Process / Ex. 5

David A Bussard
Director, Washington Division
National Center for Environmental Assessment, NCEA
ORD, USEPA

From: Bussard, David [Bussard.David@epa.gov]

Sent: 5/10/2016 6:02:04 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]

CC: Birchfield, Norman [Birchfield.Norman@epa.gov]

Subject: FA LHP calculation text

Attachments: DBcmts(ver3) on FormaldehydeTRdraft050616.docx

It could be because I am tired today, but

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

I'd like to talk about these after you and/or Jennifer have taken a look. I put down far more "red ink" than I normally like to and I realize there are often multiple ways to address when something is not clear to a reader.

David A Bussard
Director, Washington Division
National Center for Environmental Assessment, NCEA
ORD, USEPA

From: Lee, Janice [Lee.JaniceS@epa.gov]

8/26/2016 8:37:23 PM Sent:

To: Glenn, Barbara [Glenn.Barbara@epa.gov]; Cote, Ila [Cote.lla@epa.gov]; Bussard, David [Bussard.David@epa.gov]

CC: Kraft, Andrew [Kraft.Andrew@epa.gov] Subject: RE: returning your call, and a question

Attachments: Formaldehyde draft Appendices ERC May2016.docx; Formaldehyde draft Tox Review ERC May2016.docx

Yes, I do have the formaldehyde draft. and have attached it here.

Janice

From: Glenn, Barbara

Sent: Friday, August 26, 2016 4:31 PM

To: Cote, Ila <Cote.Ila@epa.gov>; Bussard, David <Bussard.David@epa.gov> Cc: Lee, Janice <Lee.JaniceS@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>

Subject: RE: returning your call, and a question

Hi Ila,

I believe that Janice has the formaldehyde draft and might be able to send it to you. If not, let me know and I'll send it on Monday.

-Barbara

From: Cote, Ila

Sent: Friday, August 26, 2016 4:22 PM

To: Bussard, David < Bussard. David@epa.gov>

Cc: Lee, Janice <Lee.JaniceS@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew

<Kraft.Andrew@epa.gov>

Subject: RE: returning your call, and a question

All of these numbers work but the 202 number is the best chance. Im switch over to working at home most of the time but still go into the office (the other two numbers). Its unpredictable where III be, so cell is the best.

Im no longer the project lead, just the task lead. In standard fashion its hard to get someone to step in. Id help but Im swamped right now with iAs and end of the year clearance.

Deliberative Process / Ex. 5

From: Bussard, David

Sent: Friday, August 26, 2016 10:49 AM To: Cote, Ila <Cote.lla@epa.gov>

Subject: returning your call, and a question

First, tried call call you on Personal Matters / Ex. 6 Is there a better number to use? I have two Personal Matters / Ex. 6

Personal Phone / Ex. 6

Second, Chris Saint has you down as "Project Lead" for Project 8 of HHRA. Is that valid? (I think Cinci has strongly resisted filling that role.)

Third, re systematic review:

- We circulated to the "ERC" the Formaldehyde Assessment, which contains descriptions of the systematic review approach taken. But, maybe you don't have that? If you don't have it, Barbara Glenn or Andrew Kraft can send it to you, and tell you which sections to focus upon.
- I assume the "Systematic Review" team already have it, but I can check with Barbara and Andrew.

Deliberative Process / Ex. 5

David A Bussard
Director, Washington Division
National Center for Environmental Assessment, NCEA
ORD, USEPA

From: Kraft, Andrew [Kraft.Andrew@epa.gov]

Sent: 3/11/2016 8:42:06 PM

To: Glenn, Barbara [Glenn.Barbara@epa.gov]

Subject: main document

Attachments: FormaldehydeTRdraft031016.docx

Hi Barbara,

I don't think I am going to get to the Appendix today, so here are my edits to the main document (not in track changes). I went through what John sent and "finalized" changes, and **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

Have a fun week without me. I probably won't be on this email much, so if you need something quickly please call or email me at my gmail address: **Personal Matters / Ex. 6**

Thanks and enjoy the new corner cubicle!

-Andrew

From: Chen, Anna [chen.anna@epa.gov]

Sent: 8/26/2016 7:39:57 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]

CC: Glenn, Barbara [Glenn.Barbara@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]

Subject: RE: JJV comments on formaldehyde... finally.. through page 249

Attachments: formaldehyde with comments 082616.docx

Hello!

I have attached the formaldehyde review with comments. It's saying the appendices file is too big, so I will try to send it in another email.

When I combined the reviews, sometimes the tables got a bit funny. For example, Table 1.1.2.-7 on page 104—each time I combined the papers, the Deliberative Process / Ex. 5 I was apprehensive to delete anything to clean it up on my own. I think that somewhat accounts for the added page length.

Comments I had to manually input are labeled with my name; the name of the reviewer is within the comment box. If you want to see comments from only Vandenberg, for example, I would select only his name and my name (and possibly "unlabeled") from the Review tab > "Show Markup" > "Specific People". You can also ctrl + F "Vandenberg" to scroll through his comments that I manually entered. Some, like Flowers, will not be listed as "Specific People" because they only had email comments I had to manually enter, so ctrl + F is the best way to find their comments that are posted under my name. This was the best I could do! I can't put in comments under anyone else's profile but mine.

Inputting comments manually (especially the emailed comments) did take a lot of time. I tried to put them where I thought the reviewer was referring to, but if you have any questions once you review them, please let me know. I can try to clarify.

Let me know if there is anything else I can do for you.

Best, Anna

From: Kraft, Andrew

Sent: Thursday, August 25, 2016 3:00 PM **To:** Chen, Anna <chen.anna@epa.gov>

Cc: Glenn, Barbara <Glenn.Barbara@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>

Subject: RE: JJV comments on formaldehyde... finally.. through page 249

Deliberative Process / Ex. 5

Thanks, Anna!

From: Chen, Anna

Sent: Thursday, August 25, 2016 2:24 PM **To:** Kraft, Andrew < Kraft. Andrew @epa.gov>

Cc: Glenn, Barbara < Glenn.Barbara@epa.gov>; Birchfield, Norman < Birchfield.Norman@epa.gov>

Subject: RE: JJV comments on formaldehyde... finally.. through page 249

Hi All,

Update: I have combined all of the comments, but now I am going to go through the review to ensure that they didn't get deleted during the process. This may take some time... but I will go through it to the best of my ability and send you what I have tomorrow.

One question: Deliberative Process / Ex. 5

Deliberative Process / Ex. 5 | can't find where those comments should go.

Let me know if you have any more comments you want me to add/combine/merge!

From: Kraft, Andrew

Sent: Monday, August 22, 2016 11:18 AM To: Chen, Anna <chen.anna@epa.gov>

Cc: Glenn, Barbara < Glenn.Barbara@epa.gov>; Birchfield, Norman < Birchfield.Norman@epa.gov>; Walker, Teneille

< Walker. Teneille@epa.gov>

Subject: Fw: JJV comments on formaldehyde... finally.. through page 249

Hi Anna,

I hate to do this, but we just received another set of comments from John Vandenberg. It looks like he only had comments through page 250, so maybe it will be easy to integrate these comments into the compiled draft you are working with? Please let us know how you think this affects your timeline.

Thanks, Andrew

From: Vandenberg, John

Sent: Saturday, August 20, 2016 10:02 AM

To: Kraft, Andrew; Glenn, Barbara; Bussard, David; Jones, Samantha **Subject:** JJV comments on formaldehyde... finally.. through page 249

All,

I must apologize profusely for not sending the comments on the draft much earlier – like more a month ago. I hope these may still be of some value. Its clear that a terrific effort has been put into this draft, to evaluate evidence and convey information as thoroughly yet concisely, and clearly as possible.

I went back through my files to find my comments on the draft, and added some edits to clarify my first run at it, hoping I could actually finish it, but I only made it through about page 250. Sorry. I also have comments on the preface that remain handwritten and too difficult to read, even for myself, that I'll try to transpose onto the draft I have. It may be that you have a newer version of the preface that I should review instead – not sure.

I'm going on vacation as soon as my wife returns in a few minutes and I'm sending this to partially clear my conscience! I'll be back in the office on Aug 29.

John

John Vandenberg National Program Director, Human Health Risk Assessment Program Division Director, National Center for Environmental Assessment U.S. Environmental Protection Agency B243-01 Research Triangle Park, NC 27711 From: Bussard, David [Bussard.David@epa.gov]

Sent: 1/12/2016 10:33:05 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]

Subject: FA: my review

Attachments: Jan 12 DB notes as to Key Issues re Dec 2015 draft.docx; Jan 12 DB cmts on FormaldehydeTRdraft12215.docx; Jan 12

DB cmts on NASPublic Comments Response_01042016.docx

Barbara and Andrew,

As you know, I think this is coming along really well.

I think I may have hit my near-term exhaustion for close reading. So, let's consider this the full extent of my current review, unless there are some portions you would flag to me that I should look at.

Deliberative Process / Ex. 5

I am happy to discuss any of these you want to discuss, and to do it just with you or to also discuss with others. Whatever would be helpful.

I almost never consider any text I write as being definitively what I want to go into the assessment. Often, it is just easier to try to jot down the kind of response or kind of text that might flow as an argument than it is to figure out how to describe why something seems like it might be improved. But, I often don't have the details in my head and I can recall things incorrectly. If I get something wrong, correct it. If it is unclear why I suggest a change, we can talk. If I suggest a change you think makes no sense, let me know.... If you get why I suggest a change, but you have a better way, suggest the better way.

Take a look, and then let's regroup on how I can help, and where you are on revisions the two of you also want to make irregardless of my input.

David

From: Bussard, David [Bussard.David@epa.gov]

Sent: 11/4/2016 1:57:04 PM

To: Birchfield, Norman [Birchfield.Norman@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara

[Glenn.Barbara@epa.gov]

Subject: FA BBDR

Attachments: plot of estimates from page r-11.pdf; Ravi Revised Main-DBcmts(5 major medium).docx; Ravi Revised Main-

DBcmts(5).docx; plot of models and data for rats.pdf

Take a look.

Deliberative Process / Ex. 5

David A Bussard
Director, Washington Division
National Center for Environmental Assessment, NCEA
ORD, USEPA

From: Bussard, David [Bussard.David@epa.gov]

Sent: 9/4/2015 10:11:42 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]

CC: Sonawane, Bob [Sonawane.Bob@epa.gov]

Subject: FA draft

Attachments: FormaldehydeTRdraft073015_DBcmts on DR.docx

Andrew and Barbara,

Deliberative Process / Ex. 5

I have not read the cancer text yet.

David A Bussard
Director, Washington Division
National Center for Environmental Assessment, NCEA
ORD, USEPA

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 9/22/2017 4:06:01 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

I be calling in from my home

From: Kraft, Andrew

Sent: Friday, September 22, 2017 11:43 AM **To:** Glenn, Barbara <Glenn.Barbara@epa.gov>

Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

remote from home, or from Tina's office? If you are going to be remote from Tina's office, I will probably just join you there (from previous conversations, it sounded like Tina wanted it to be remote-only). Happy Friday!

From: Glenn, Barbara

Sent: Friday, September 22, 2017 11:30 AM

To: Bahadori, Tina; Kraft, Andrew; Thayer, Kris; Lavoie, Emma; Ramasamy, Santhini; Jones, Samantha; Ross, Mary;

Hagerthey, Scot

Cc: Bussard, David; D'Amico, Louis

Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

I will need to join remotely. Thanks.

From: Bahadori, Tina

Sent: Friday, September 22, 2017 11:23 AM

To: Kraft, Andrew < Kraft.Andrew@epa.gov >; Thayer, Kris < thayer.kris@epa.gov >; Lavoie, Emma < Lavoie.Emma@epa.gov >; Ramasamy, Santhini < Ramasamy.Santhini@epa.gov >; Jones, Samantha

 <Jones.Samantha@epa.gov>; Ross, Mary < Ross.Mary@epa.gov>; Hagerthey, Scot < Hagerthey.Scot@epa.gov>

Cc: Bussard, David <Bussard.David@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; D'Amico, Louis

<<u>DAmico.Louis@epa.gov</u>>

Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Deliberative Process / Ex. 5

On Monday, we were going to go in person to RRB for the briefing, although I have reserved my conference room with video connection, if you or anyone would prefer to do it remotely. I think either way is fine.

From: Kraft, Andrew

Sent: Friday, September 22, 2017 11:15 AM

To: Thayer, Kris < thayer.kris@epa.gov; Bahadori, Tina Bahadori.Tina@epa.gov; Lavoie, Emma Lavoie, EmmaLavoie.Emma@epa.gov; Jones, Samantha

<<u>Jones.Samantha@epa.gov</u>>; Ross, Mary <<u>Ross.Mary@epa.gov</u>>; Hagerthey, Scot <<u>Hagerthey.Scot@epa.gov</u>>

Cc: Bussard, David < <u>Bussard.David@epa.gov</u>>; Glenn, Barbara < <u>Glenn.Barbara@epa.gov</u>>; D'Amico, Louis

<DAmico.Louis@epa.gov>

Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Chatting on Monday might be tough-I have meetings stacked until 4, and Barbara is leaving to teach a class around 3. Maybe it's a break time during SAB (after our ppts)-type talk?

Also, we are all just planning on attending the briefing remotely on Monday, correct (i.e. no one is going over in person)?

From: Thayer, Kris

Sent: Friday, September 22, 2017 7:44 AM

To: Kraft, Andrew; Bahadori, Tina; Lavoie, Emma; Ramasamy, Santhini; Jones, Samantha; Ross, Mary; Hagerthey, Scot

Cc: Bussard, David; Glenn, Barbara; D'Amico, Louis

Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Let's discuss how best to respond after Monday briefing....

From: Kraft, Andrew

Sent: Friday, September 22, 2017 7:43 AM

To: Bahadori, Tina <<u>Bahadori.Tina@epa.gov</u>>; Lavoie, Emma <<u>Lavoie.Emma@epa.gov</u>>; Ramasamy, Santhini

<Ramasamy.Santhini@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>;

Hagerthey, Scot < Hagerthey. Scot@epa.gov>

Cc: Bussard, David <Bussard.David@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Glenn, Barbara

<<u>Glenn.Barbara@epa.gov</u>>; D'Amico, Louis <<u>DAmico.Louis@epa.gov</u>>

Subject: Fw: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Just forwarding this to the wider group that was asked to weigh in on the prior email. Please see below.

From: Lidka Maslankiewicz < lidka.maslankiewicz@rivm.nl>

Sent: Friday, September 22, 2017 4:54 AM

To: Kraft, Andrew

Cc: Bussard, David; D'Amico, Louis; Els Smit; Glenn, Barbara; Joke Herremans; Paul Janssen; Thayer, Kris; Theo Vermeire

Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Andrew and Barbara

Thank you for your reply, apologies for not answering sooner.

The issue is that we would like to use the data as presented in the 2010 Draft, more specifically the quantification of cancer risks for NPC (Nasopharyngeal Cancer), based either on human data and on animal data.

From your mail, we understand that the information is not to be cited as the EPA position. That was not our intention, but rather we want to include the unit risks as a scientific approach that has been developed and that we need to take on board.

Could it be possible to use the information, if we explicitly include a disclaimer? Something in line with: "It should be noted that the methodology used for the quantification of cancer risk for NPC (Nasopharyngeal Cancer), has not been formalised and should not be seen as the official position of the EPA. From a scientific viewpoint, however, we consider this approach as valid and use unit risk to derive the Maximum Permissible Risk (MPR)."

We also noted that in 2014 US-EPA convened a workshop (https://www.epa.gov/sites/production/files/2014-12/documents/formaldehyde_workshop_agenda_final.pdf), the topics of which were the endogenous formation of formaldehyde and its relation to formaldehyde toxicity and the mechanistic evidence for lymphohematopoietic cancer induction by formaldehyde. Any further information on these topics and on the envisaged timeline for finalization of the US-EPA IRIS evaluation would be very welcome.

April 30th to May 1st, 2014 Crystal City Marriott at ...

www.epa.gov

Luoping Zhang, University of California at Berkeley, discussant Robert Snyder, Rutgers University (retired), discussant Martha Sandy, California EPA, discussant

Maybe we can first do the exchange via mail and decide later on if a telephone conference is useful.

Kind regards

Lidka

Lidka Maslankiewicz National Institute for Public Health and the Environment (RIVM) Centre for Safety of Substances and Products tel. 31 (0)30 2743160 +31 6 46 86 07 73 fax. 31 (0)30 2744401

e-mail: Lidka.Maslankiewicz@rivm.nl

From: "Kraft, Andrew" < Kraft. Andrew@epa.gov>

To: Lidka Maslankiewicz < lidka.maslankiewicz@rivm.nl>,

Co: Els Smit <<u>els.smit@rivm.nl</u>>, Paul Janssen <<u>paul.janssen@rivm.nl</u>>, "Joke Herremans" <<u>joke.herremans@rivm.nl</u>>, "Glenn, Barbara"

<Glenn Barbara@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Bussard, David" <Bussard David@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>

Date: 09/08/2017 05:21 PM

Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hi Lidka,

Barbara (Glenn) and I are the current chemical managers of the formaldehyde assessment. We were hoping we might be able to set up a phone conversation to talk through the current status of the assessment and your questions below? If so, I can send out some type of Google poll or similar to find a time that works for everyone who might want to participate?

I would emphasize to you that the draft you mention was never finalized after it was released for the purposes of peer consultation and review. Thus, it should not be cited as an EPA position. We can explain this in greater detail when we talk.

We look forward to future conversations, Andrew and Barbara

From: Lidka Maslankiewicz < lidka.maslankiewicz@rivm.nl>

Sent: Tuesday, August 29, 2017 7:59 AM

To: Kraft, Andrew

Cc: Els Smit; Paul Janssen; Joke Herremans

Subject: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Dr Kraft,

My name is Lidka Maslankiewicz and I work at the Dutch National Institute for Public Health and the Environment (RIVM). We are currently busy with the update of the Maximum Permissible Risk (MPR) for formaldehyde.

We would like to use the approach and values described in IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010), in particular Volume 3: "Quantitative Assessment, Major Conclusions in the Characterization of Hazard and Dose Response"

(https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614), to derive MPR value for the Netherlands. Could you, please, inform me, if this could be permitted? Are there more recent versions of this document? If we would be allowed to use your data, how we could refer to the source?

IRIS Toxicological Review of Formaldehyde (Inhalation ... cfpub.epa.gov EPA announces the release of the Toxicological Review of Formaldehyde-Inhalation Assessment in the June 2, 2010 Federal Register Notice. This draft assessment is ... IRIS Toxicological Review of Formaldehyde (Inhalation ... cfpub.epa.gov EPA announces the release of the Toxicological Review of Formaldehyde-Inhalation Assessment in the June 2, 2010

Kind regards
Lidka
Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products
tel. 31 (0)30 2743160
+31 6 46 86 07 73
fax. 31 (0)30 2744401

Federal Register Notice. This draft assessment is ...

e-mail: Lidka.Maslankiewicz@rivm.nl

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

www.rivm.ni De zorg voor morgen begint vandaag

RIVM
www.rivm.nl
Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en
wetenschappelijke onderbouwing van het volksgezondheidsbeleid. Ook valt het
informatiecentrum

This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message. RIVM accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages.

www.rivm.nl/en Committed to health and sustainability

Rijksinstituut voor Volksgezondheid en Milieu - RIVM
www.rivm.nl
Dutch experts on climate change adaptation join forces. Fourteen Dutch
knowledge institutes have joined forces to provide practical, demand-driven
policy advice based

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

www.rivm.nl De zorg voor morgen begint vandaag

RIVM
www.rivm.nl
Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en
wetenschappelijke onderbouwing van het volksgezondheidsbeleid. Ook valt het
informatiecentrum

This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message. RIVM accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages.

www.rivm.nl/en Committed to health and sustainability

Rijksinstituut voor Volksgezondheid en Milieu - RIVM
<u>www.rivm.nl</u>
Dutch experts on climate change adaptation join forces. Fourteen Dutch
knowledge institutes have joined forces to provide practical, demand-driven
policy advice based

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten. www.rivm.ni De zorg voor morgen begint vandaag

This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message. RIVM accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages. www.rivm.nl/en Committed to health and sustainability

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 5/21/2015 3:54:18 PM

To: Barbara Glenn Personal Matters / Ex. 6 Glenn, Barbara [Glenn.Barbara@epa.gov]

Subject: Intro and methods

Attachments: IntroMethods_051915.docx

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 5/1/2015 9:05:00 PM

To: Barbara Glenn Personal Matters / Ex. 6

Subject: front section

Attachments: HCHO_FrontMatter_050115.docx

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 4/18/2017 7:28:23 PM

To: Personal Matters / Ex. 6 µ; Kraft, Andrew [Kraft.Andrew@epa.gov]

CC: D'Amico, Louis [DAmico.Louis@epa.gov]

Subject: RE: Regarding the IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010)

Hello Mr. French,

I apologize for not getting back to you before now. You are correct that there is no RfC on the IRIS database for formaldehyde, and the External Review Draft from 2010 cannot be cited. In fact, the formaldehyde assessment has undergone an extensive revision since then and is not yet final.

*However, the ATSDR (Agency for Toxic Substances and Disease Registry) develops toxicity values for noncancer endpoints and has done so for formaldehyde. These are MRLs (minimum risk levels) and are directed at specified exposure durations (acute, intermediate and chronic). There also is a technical document. Here is the link. https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=39

Good luck with your capstone.

Regards, Barbara Glenn

From: Personal Matters / Ex. 6

Sent: Tuesday, April 11, 2017 1:08 AM

To: Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>

Subject: Regarding the IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010)

Hello,

My name is Roberto French, I am a current senior undergraduate student studying Environmental Public Health at the Ohio State University. I am attempting to write, and potentially publish, a research thesis as a part of my honors final capstone experience. I am researching the non-cancer health effects of formaldehyde present in embalming fluid as it pertains to gross anatomy laboratories, this led me to trying to find an inhalation RfC for formaldehyde, which was not present on the IRIS Chemical Database. Upon doing some further research, I came across the IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010) which provided a number of potential inhalation RfCs, I have attached that same draft document to this email. As this document is a draft however, it cannot be cited, and so I'm a little stuck as to where to progress regarding finding an inhalation RfC for formaldehyde. I am emailing you to ask if there is any help you may provide me with in regards to this problem, any and all help would be greatly appreciated.

Thank you, Roberto French

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 7/10/2017 6:16:58 PM

To: Personal Matters / Ex. 6

CC: Glenn, Barbara [Glenn.Barbara@epa.gov]

Subject: ML

Attachments: Formaldehyde Main Text 053017_071017.docx

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 3/16/2017 8:27:13 PM

To: Jinot, Jennifer [Jinot.Jennifer@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: RE: Formaldehyde - expedited review request

Attachments: Van Landingham 2016.pdf

Hi Jennifer,

It's fine to put them in the document in track changes.

Deliberative Process / Ex. 5

From: Jinot, Jennifer

Sent: Thursday, March 16, 2017 3:59 PM

To: Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>

Subject: RE: Formaldehyde - expedited review request

Deliberative Process / Ex. 5

From: Glenn, Barbara

Sent: Tuesday, March 14, 2017 8:51 AM

To: Vulimiri, Suryanarayana <\footnotesia.Sury@epa.gov>; Makris, Susan <\footnotesia.Susan@epa.gov>; Salazar, Keith <\footnotesia.Susan@epa.gov>; Fritz, Jason <\footnotesia.Susan@epa.gov>; Bateson, Thomas <\footnotesia.Susan@epa.gov>; Jinot, Jennifer <\footnotesia.Susan@epa.gov>; Subramaniam, Ravi <\footnotesia.Susan@epa.gov>; Whalan, John <\footnotesia.Susan@epa.gov>; Whalan, John@epa.gov>

Cc: Birchfield, Norman Bussard, David Bussard.David@epa.gov; Kraft, Andrew Kraft, Andrew@epa.gov

Subject: Formaldehyde - expedited review request

Hello Team,

Some updates on the assessment and a <u>request for your expedited review</u>.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Please send an email or call if you want to discuss anything. The pace has picked up.

Regards, Barbara and Andrew

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 6/9/2015 4:32:28 PM

To: Cooper, Glinda [Cooper.Glinda@epa.gov]

Subject: RE: B4 introduction

Attachments: IntroMethods_051915.docx

I included a discussion on exposure in the introduction. Here is the intro.

----Original Message-----From: Cooper, Glinda

Sent: Tuesday, June 09, 2015 12:16 PM

To: Glenn, Barbara

Subject: RE: B4 introduction

Deliberative Process / Ex. 5

----Original Message----

From: Glenn, Barbara Sent: Tuesday, June 09, 2015 8:44 AM

To: Cooper, Glinda Cc: Kraft, Andrew

Subject: RE: B4 introduction

Hi Glinda,

Deliberative Process / Ex. 5

----Original Message---From: Cooper, Glinda

Sent: Monday, June 08, 2015 2:33 PM To: Glenn, Barbara

To: Glenn, Barbara Cc: Cooper, Glinda Subject: B4 introduction

Deliberative Process / Ex. 5

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 3/9/2017 9:12:59 PM

To: Birchfield, Norman [Birchfield.Norman@epa.gov]

Subject: FW: Boomerang -- Letter Submitted on Behalf of the ACC Formaldehyde Panel Attachments: Letter to EPA NCEA Director on Formaldehyde IRIS - Final- 03 07 17.pdf

From: Bahadori, Tina

Sent: Thursday, March 09, 2017 4:23 AM

To: Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis

<DAmico.Louis@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Hagerthey,

Scot <Hagerthey.Scot@epa.gov>

Subject: Boomerang -- Letter Submitted on Behalf of the ACC Formaldehyde Panel

Dear Barbara and Andrew,

Deliberative Process / Ex. 5

Thanks, Tina

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Tuesday, March 7, 2017 8:16 AM

To: Bahadori, Tina < Bahadori.Tina@epa.gov >
Cc: Kavlock, Robert < Kavlock.Robert@epa.gov >

Subject: Letter Submitted on Behalf of the ACC Formaldehyde Panel

Dear Dr. Bahadori:

Please find attached a letter submitted on behalf of the American Chemistry Council Formaldehyde Panel.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

mericanchemistry.com			

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 6/20/2018 6:00:09 PM

To: Soto, Vicki [Soto.Vicki@epa.gov]; 'Carter, Greg' [Greg.Carter@icf.com]

CC: Samuels, Crystal [Samuels.Crystal@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Kellar, Penelope

[Penelope.Kellar@icf.com]

Subject: RE: work request Task 1 WA 4-17 - IRIS Toxicological Review of Formaldehyde

Hi Vicki and Greg,

Yes that is correct. If it is easy to adjust column width or something else to shorten tables, please do so.

Thanks, Barbara

From: Soto, Vicki

Sent: Wednesday, June 20, 2018 1:31 PM **To:** 'Carter, Greg' < Greg. Carter@icf.com >

Cc: Samuels, Crystal <Samuels.Crystal@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Kellar, Penelope <Penelope.Kellar@icf.com>; Soto, Vicki <Soto.Vicki@epa.gov>

Subject: RE: work request Task 1 WA 4-17 - IRIS Toxicological Review of Formaldehyde

Greg - I'm so sorry for the delay. See my responses below....

Vicki

Barbara – one for you, but I think that you had asked that they close up space if possible.

From: Carter, Greg [mailto:Greg.Carter@icf.com]

Sent: Tuesday, June 19, 2018 10:51 AM To: Soto, Vicki <Soto, Vicki@epa.gov>

Cc: Samuels, Crystal <Samuels.Crystal@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara

<<u>Glenn.Barbara@epa.gov></u>; Kellar, Penelope <<u>Penelope.Kellar@icf.com></u>

Subject: RE: work request Task 1 WA 4-17 - IRIS Toxicological Review of Formaldehyde

Thanks for this Vicki,

See below, in red, some requests for clarification.

gc

From: Soto, Vicki [mailto:Soto.Vicki@epa.gov]
Sent: Wednesday, June 13, 2018 4:43 PM
To: Carter, Greg <Greg.Carter@icf.com>

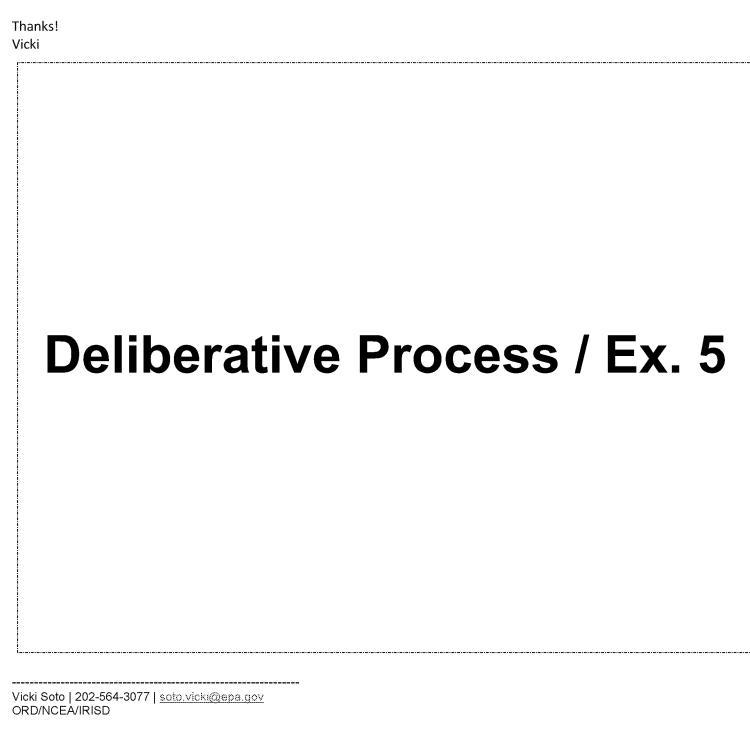
Cc: Samuels, Crystal < Samuels. Crystal@epa.gov>; Kraft, Andrew < Kraft. Andrew@epa.gov>; Glenn, Barbara

<<u>Glenn.Barbara@epa.gov</u>>; Soto, Vicki <<u>Soto.Vicki@epa.gov</u>>

Subject: work request Task 1 WA 4-17 - IRIS Toxicological Review of Formaldehyde

Hi Greg,

Attached is the work request form for Formaldehyde. Please look it over and let me know if I missed anything. Send me your "email" addresses and we will get you access to the files. I forgot to put "add line numbers" in the documents also. Format document as an Agency Review draft.



Mailing Address:

USEPA Headquarters | William Jefferson Clinton Building | 1200 Pennsylvania Avenue, N.W. | MC: 8602R | Washington, DC 20460

Delivery Address:

USEPA Headquarters | William Jefferson Clinton Building | 1300 Pennsylvania Avenue, N.W. | MC: 8602R | Washington, DC 20460

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 11/7/2016 4:05:41 PM

To: Subramaniam, Ravi [subramaniam.ravi@epa.gov]

CC: Kraft, Andrew [Kraft.Andrew@epa.gov]
Subject: Meeting today with Ramboll reps

Attachments: Final New Formaldehyde Science Ramboll Environ_110716_final.pdf

Hi Ravi,

You may not be back at work yet but I wanted to share with you the slides that Ken Mundt and Robinan Gentry are using during our meeting with them about their activities. The meeting is at 2 pm in rm 11100. : Personal Matters / Ex. 6 | Conference code: Personal Matters / Ex. 6 |

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 5/9/2018 1:16:14 PM

To: Lidka Maslankiewicz [lidka.maslankiewicz@rivm.nl]

Subject: RE: Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS Toxicological

Review of Formaldehyde (Inhalation))

Here is a number

Personal Matters / Ex. 6 I'm not sure of the US code

From: Lidka Maslankiewicz [mailto:lidka.maslankiewicz@rivm.nl]

Sent: Wednesday, May 09, 2018 9:08 AM **To:** Glenn, Barbara <Glenn.Barbara@epa.gov>

Subject: RE: Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS

Toxicological Review of Formaldehyde (Inhalation))

Or you could call +31 646860773

Lidka Maslankiewicz

National Institute for Public Health and the Environment (RIVM) Centre for Safety of Substances and Products Antonie van Leeuwenhoeklaan 9 | 3721 MA Bilthoven Postbus 1 | 3720 BA Bilthoven

tel. 31 (0)30 2743160 +31 6 46 86 07 73 fax. 31 (0)30 2744401

e-mail: Lidka.Maslankiewicz@rivm.nl

From: "Glenn, Barbara" < Glenn.Barbara@epa.gov >

To: Lidka Maslankiewicz/RIVM/NL < lidka maslankiewicz@rivm.nl>,

Date: 05/09/2018 03:02 PM

Subject: RE: Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS Toxicological Review of Formaldehyde

(Inhalation))

Hi Lidka,

The number you gave we are getting a message that it is not in service. Did you give me all the numbers I need to dial an international callk?

----Original Appointment----

From: Lidka Maslankiewicz/RIVM/NL [mailto:lidka.maslankiewicz@rivm.nl]

Sent: Monday, April 09, 2018 8:30 AM

To: Lidka Maslankiewicz/RIVM/NL; Glenn, Barbara; Kraft, Andrew; Paul Janssen/RIVM/NL; Theo Vermeire/RIVM/NL

Subject: Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS Toxicological Review of

Formaldehyde (Inhalation))

When: Wednesday, May 09, 2018 3:00 PM-4:30 PM W. Europe.

Where:

Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS Toxicological Review of Formaldehyde (Inhalation))	è
05/09/2018 -	
No Location Information	

		Τ				

Agenda: 1. Round of mutual introduction 2. Presentation of US EPA and NL ongoing activities on formaldehyde risk assessment. 3. NL questions on 2010 draft IRIS toxicological review on formaldehyde: • Are there any new developments in the process at EPA of evaluating formaldehyde? • Would it be possible for us to use the data and concept, with agreed referencing? • Do you plan any additional modelling to be done for deriving the unit risks from the NCI-cohort data, according to the advice from National Research Council? • Do you plan to derive unit risk derived from animal data? 4. AOB

Please, call:

+31 30 274 3160

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

www.rivm.ni De zorg voor morgen begint vandaag

This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message. RIVM accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages.

www.rivm.ni/en Committed to health and sustainability

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 9/3/2015 7:37:24 PM

To: Gibbons, Catherine [Gibbons.Catherine@epa.gov]

CC: Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: formaldehyde example

 $\textbf{Attachments}: \quad Formaldehyde TR draft 073015. docx; Formaldehyde Appendix draft _081115. docx$

Hi Catherine,
Here is our TR and appendices.

Deliberative Process / Ex. 5
I hope it is helpful.

-Barbara

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 6/21/2016 4:24:19 PM

To: Bussard, David [bussard.david@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]

CC: Kraft, Andrew [Kraft.Andrew@epa.gov]
Subject: FW: marginal comments main text (RFc)

Attachments: Formaldehyde draft Tox Review ERC May2016.lk.docx

Email #2

From: Kopylev, Leonid

Sent: Thursday, June 09, 2016 3:04 PM

To: Glenn, Barbara <Glenn.Barbara@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov>; Morozov, Viktor < Morozov. Viktor@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>

Subject: marginal comments main text (RFc)

Barbara,

Deliberative Process / Ex. 5

Hope this helps and please let me know if any of my comments are unclear.

Thanks,

Leonid

From: Glenn, Barbara

Sent: Thursday, June 09, 2016 2:11 PM

To: Kopylev, Leonid < Kopylev. Leonid@epa.gov>; Bateson, Thomas < Bateson. Thomas@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov>; Morozov, Viktor < Morozov. Viktor@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>

Subject: RE: intermediate report on non-cancer formaldehyde analyses and also comment on study tables

Hi Leonid.

Thank you very much. We appreciate your careful feedback.

-Barbara

From: Kopylev, Leonid

Sent: Thursday, June 09, 2016 11:20 AM

To: Bateson, Thomas Bateson, Thomas@epa.gov; Glenn, Barbara Glenn, Barbara@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov>; Morozov, Viktor < Morozov. Viktor@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>

Subject: intermediate report on non-cancer formaldehyde analyses and also comment on study tables

Tom:

I have reviewed documentation for the non-cancer quantitative work. There is a lot of creativity (in a good meaning of the word!) here.

Deliberative Process / Ex. 5

100.					
Ba	P 3/4	2.5	800	**	>
Por C.S	1 3.5	CI	В	SCI	٠

I should start with that the amount of reviewed literature is truly impressive!

Deliberative Process / Ex. 5

Hope this intermediate report helps! Leonid

AWL till Tuesday, in office next Wednesday

From: Glenn, Barbara

Sent: Friday, June 03, 2016 2:45 PM

To: Jones, Samantha < Jones. Samantha@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov >; Hogan, Karen < Hogan, Karen@epa.gov >; Kopylev, Leonid

<Kopylev.Leonid@epa.gov>

Subject: Documentation for derivation of BMC and BMCL for formaldehyde noncancer endpoints

Hi Samantha,

I've cc:d Karen and Leonid as they will be reviewing the noncancer dose-response section for human and animal

data. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thank you for reviewing formaldehyde!

Barbara and Andrew

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 5/11/2016 7:57:18 PM

To: Jinot, Jennifer [Jinot.Jennifer@epa.gov]

CC: Bussard, David [bussard.david@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: David's comments on cancer d-r

Attachments: DBcmts(ver4) on FormaldehydeTRdraft050616.docx

Hi Jennifer,

In preparation for sending the draft assessment for review by the ERC on May 20th, Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

I've sent the document that he reviewed. In order to get the changes into our working document, if you send this one to Andrew or me with the track changes showing, we will know what parts to paste in.

Thank you, Barbara

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 7/23/2015 9:16:01 PM

To: Bussard, David [bussard.david@epa.gov]; Sonawane, Bob [Sonawane.Bob@epa.gov]
CC: Kraft, Andrew [Kraft.Andrew@epa.gov]; Hagerthey, Scot [Hagerthey.Scot@epa.gov]

Subject: Formaldehyde TR with more sections
Attachments: FormaldehydeTRdraft072315.docx

Hi David,

I have added some more sections to the draft assessment. Its attached and also on the L drive

Deliberative Process / Ex. 5

It's a pretty cumbersome document.

Deliberative Process / Ex. 5

Thanks, Barbara

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 7/16/2015 5:50:57 PM

To: Sonawane, Bob [Sonawane.Bob@epa.gov]; Bussard, David [bussard.david@epa.gov]

CC: Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: Draft Formaldehyde Hazard Section Compiled

Attachments: FormaldehydeTRdraft071615.docx

Hi David and Bob,

Deliberative Process / Ex. 5

It will be easier to move around the document if you open the navigation pane (go to "view" in the menu and click the box by navigation pane). This will reveal a list on the left of the headings in each section – like a table of contents. You can click on a heading and be taken right to it. Since the headings are not linked to the table of contents, this is blank so the navigation pane is serving as a table of contents at this point.

The formating is not exactly standardized although I did attempt to reformat the majority of the document in the IRIS TR styles so it would not be too distracting. There is still a lot of nonIRIS TR formats in the document.

The document is also in the L drive in the formaldehyde folder under 2015 compiled. We will be continuing to revise and add to this over the next several weeks.

-Barbara and Andrew

From: Chen, Anna [chen.anna@epa.gov]

Sent: 8/26/2016 7:41:22 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]

CC: Glenn, Barbara [Glenn.Barbara@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]

Subject: RE: JJV comments on formaldehyde... finally.. through page 249

Attachments: Appendices with comments 082616.docx

Here are the appendices!

Anna

From: Kraft, Andrew

Sent: Thursday, August 25, 2016 3:00 PM **To:** Chen, Anna <chen.anna@epa.gov>

Cc: Glenn, Barbara <Glenn.Barbara@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>

Subject: RE: JJV comments on formaldehyde... finally.. through page 249

Deliberative Process / Ex. 5

Thanks, Anna!

From: Chen, Anna

Sent: Thursday, August 25, 2016 2:24 PM **To:** Kraft, Andrew < Kraft. Andrew @epa.gov>

Cc: Glenn, Barbara < Glenn.Barbara@epa.gov >; Birchfield, Norman < Birchfield.Norman@epa.gov >

Subject: RE: JJV comments on formaldehyde... finally.. through page 249

Hi All,

Update: I have combined all of the comments, but now I am going to go through the review to ensure that they didn't get deleted during the process. This may take some time... but I will go through it to the best of my ability and send you what I have tomorrow.

One question Deliberative Process / Ex. 5

Deliberative Process / Ex. 5 | can't find where those comments should go.

Let me know if you have any more comments you want me to add/combine/merge!

From: Kraft, Andrew

Sent: Monday, August 22, 2016 11:18 AM To: Chen, Anna < chen.anna@epa.gov>

Cc: Glenn, Barbara < Glenn.Barbara@epa.gov >; Birchfield, Norman < Birchfield.Norman@epa.gov >; Walker, Teneille

<Walker.Teneille@epa.gov>

Subject: Fw: JJV comments on formaldehyde... finally.. through page 249

Hi Anna,

I hate to do this, but we just received another set of comments from John Vandenberg. It looks like he only had comments through page 250, so maybe it will be easy to integrate these comments into the compiled draft you are working with? Please let us know how you think this affects your timeline.

Thanks, Andrew

From: Vandenberg, John

Sent: Saturday, August 20, 2016 10:02 AM

To: Kraft, Andrew; Glenn, Barbara; Bussard, David; Jones, Samantha **Subject:** JJV comments on formaldehyde... finally.. through page 249

All,

I must apologize profusely for not sending the comments on the draft much earlier – like more a month ago. I hope these may still be of some value. Its clear that a terrific effort has been put into this draft, to evaluate evidence and convey information as thoroughly yet concisely, and clearly as possible.

I went back through my files to find my comments on the draft, and added some edits to clarify my first run at it, hoping I could actually finish it, but I only made it through about page 250. Sorry. I also have comments on the preface that remain handwritten and too difficult to read, even for myself, that I'll try to transpose onto the draft I have. It may be that you have a newer version of the preface that I should review instead — not sure.

I'm going on vacation as soon as my wife returns in a few minutes and I'm sending this to partially clear my conscience! I'll be back in the office on Aug 29.

John

John Vandenberg
National Program Director, Human Health Risk Assessment Program
Division Director, National Center for Environmental Assessment
U.S. Environmental Protection Agency
B243-01
Research Triangle Park, NC 27711

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]

Sent: 9/1/2015 4:31:13 PM

To: Bussard, David [Bussard.David@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]

CC: Sonawane, Bob [Sonawane.Bob@epa.gov]

Subject: RE: ADAFs and combining risks

Attachments: Formaldehyde_Cancer_DR_071913-jj2_bgAug2014.docx

This is what we have as our current version. Jennifer was not happy with some of the text which she is going to revise, but the calculations were not changed from her dec draft and it is all in there.

From: Bussard, David

Sent: Tuesday, September 01, 2015 11:51 AM

To: Glenn, Barbara; Kraft, Andrew

Cc: Sonawane, Bob

Subject: Fwd: ADAFs and combining risks

let me know if it is not in your current draft. (I can't send attachment easily from my iPhone)

David Bussard

Sent from my iPhone

Begin forwarded message:

From: "Jinot, Jennifer" < <u>Jinot.Jennifer@epa.gov</u>>
To: "Bussard, David" < <u>Bussard.David@epa.gov</u>>
Cc: "Jinot, Jennifer" < <u>Jinot.Jennifer@epa.gov</u>>
Subject: RE: ADAFs and combining risks

yes, actually, i had done all this in a draft i submitted back in Dec 2014. i'm not sure what's in the current working draft.

i attached my Dec 2014 draft. the relevant sections are 2.2.4.1, 2.2.4.3, and 2.2.4.4, in particular pages 2-558 to 2-559.

From: Bussard, David

Sent: Tuesday, September 01, 2015 10:16 AM

To: Jinot, Jennifer

Subject: RE: ADAFs and combining risks

Thanks Jennifer,

Is that currently in the draft FA reassessment?

David

From: Jinot, Jennifer

Sent: Tuesday, September 01, 2015 10:08 AM

To: Bussard, David

Subject: RE: ADAFs and combining risks

Deliberative Process / Ex. 5

ii

From: Bussard, David

Sent: Tuesday, September 01, 2015 8:18 AM

To: Jinot, Jennifer

Subject: ADAFs and combining risks

Jennifer,

Deliberative Process / Ex. 5

David

<FormaldehydeTRdraft071913-jj2.docx>

From: Jinot, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D0EDF66A00054AFE84F4AB5C5119562F-JINOT, JENNIFER]

Sent: 11/16/2016 6:44:15 PM
To: Personal Matters / Ex. 6
Subject: formaldehyde paper

Attachments: Van Landingham et al. 2016.pdf

hi. if you can possibly read this paper over the next 2-3 days, i'd like to discuss it with you, ideally before this Monday. thanks. j

From: Jinot, Jennifer [Jinot.Jennifer@epa.gov]

Sent: 9/1/2015 3:19:53 PM

To: Bussard, David [Bussard.David@epa.gov]
CC: Jinot, Jennifer [Jinot.Jennifer@epa.gov]

Subject: RE: ADAFs and combining risks **Attachments**: FormaldehydeTRdraft071913-jj2.docx

yes, actually, i had done all this in a draft i submitted back in Dec 2014. i'm not sure what's in the current working draft i attached my Dec 2014 draft. the relevant sections are 2.2.4.1, 2.2.4.3, and 2.2.4.4, in particular pages 2-558 to 2-559. jj

From: Bussard, David

Sent: Tuesday, September 01, 2015 10:16 AM

To: Jinot, Jennifer

Subject: RE: ADAFs and combining risks

Thanks Jennifer,

Is that currently in the draft FA reassessment?

David

From: Jinot, Jennifer

Sent: Tuesday, September 01, 2015 10:08 AM

To: Bussard, David

Subject: RE: ADAFs and combining risks

Deliberative Process / Ex. 5

From: Bussard, David

Sent: Tuesday, September 01, 2015 8:18 AM

To: Jinot, Jennifer

Subject: ADAFs and combining risks

Jennifer,

Deliberative Process / Ex. 5

David

From: Glenn, Barbara [Glenn.Barbara@epa.gov]

Sent: 6/21/2016 4:24:19 PM

To: Bussard, David [Bussard.David@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]

CC: Kraft, Andrew [Kraft.Andrew@epa.gov]
Subject: FW: marginal comments main text (RFc)

Attachments: Formaldehyde draft Tox Review ERC May2016.lk.docx

Email #2

From: Kopylev, Leonid

Sent: Thursday, June 09, 2016 3:04 PM

To: Glenn, Barbara <Glenn.Barbara@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov>; Morozov, Viktor < Morozov. Viktor@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>

Subject: marginal comments main text (RFc)

Barbara,

Deliberative Process / Ex. 5

Hope this helps and please let me know if any of my comments are unclear.

Thanks, Leonid

From: Glenn, Barbara

Sent: Thursday, June 09, 2016 2:11 PM

To: Kopylev, Leonid < Kopylev, Leonid@epa.gov>; Bateson, Thomas < Bateson. Thomas@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov>; Morozov, Viktor < Morozov. Viktor@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>

Subject: RE: intermediate report on non-cancer formaldehyde analyses and also comment on study tables

Hi Leonid,

Thank you very much. We appreciate your careful feedback.

-Barbara

From: Kopylev, Leonid

Sent: Thursday, June 09, 2016 11:20 AM

To: Bateson, Thomas Bateson, Thomas@epa.gov; Glenn, Barbara Glenn, Barbara@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov>; Morozov, Viktor < Morozov. Viktor@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>

Subject: intermediate report on non-cancer formaldehyde analyses and also comment on study tables

Tom:

I have reviewed documentation for the non-cancer quantitative work. There is a lot of creativity (in a good meaning of the word!) here.

Deliberative Process / Ex. 5

Barbara:

I should start with that the amount of reviewed literature is truly impressive!

Deliberative Process / Ex. 5

Hope this intermediate report helps! Leonid AWL till Tuesday, in office next Wednesday From: Glenn, Barbara

Sent: Friday, June 03, 2016 2:45 PM

To: Jones, Samantha < Jones. Samantha@epa.gov>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov >; Hogan, Karen < Hogan, Karen@epa.gov >; Kopylev, Leonid

<Kopylev.Leonid@epa.gov>

Subject: Documentation for derivation of BMC and BMCL for formaldehyde noncancer endpoints

Hi Samantha,

I've cc:d Karen and Leonid as they will be reviewing the noncancer dose-response section for human and animal data.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

There are other studies with data that were modeled as well, and the documentation was included in the draft supplemental materials that was provided for ERC review.

Thank you for reviewing formaldehyde!

Barbara and Andrew

From: Glenn, Barbara [Glenn.Barbara@epa.gov]

Sent: 3/14/2017 6:05:17 PM

To: Bateson, Thomas [Bateson.Thomas@epa.gov]
CC: Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: FW: Boomerang -- Letter Submitted on Behalf of the ACC Formaldehyde Panel Attachments: Letter to EPA NCEA Director on Formaldehyde IRIS - Final- 03 07 17.pdf

Here is the letter that Tina forwarded which I assume is the same as the one in Inside EPA

From: Bahadori, Tina

Sent: Thursday, March 09, 2017 4:23 AM **To:** Glenn, Barbara; Kraft, Andrew

Cc: Ross, Mary; Jones, Samantha; D'Amico, Louis; Thayer, Kris; Bussard, David; Hagerthey, Scot

Subject: Boomerang -- Letter Submitted on Behalf of the ACC Formaldehyde Panel

Dear Barbara and Andrew,

Deliberative Process / Ex. 5

Thanks, Tina

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Tuesday, March 7, 2017 8:16 AM **To:** Bahadori, Tina < <u>Bahadori, Tina@epa.gov</u>> **Cc:** Kavlock, Robert < Kavlock, Robert@epa.gov>

Subject: Letter Submitted on Behalf of the ACC Formaldehyde Panel

Dear Dr. Bahadori:

Please find attached a letter submitted on behalf of the American Chemistry Council Formaldehyde Panel.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

From: Kraft, Andrew [Kraft.Andrew@epa.gov]

Sent: 9/8/2017 3:36:02 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: Fw: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

From: Kraft, Andrew

Sent: Friday, September 8, 2017 11:31 AM

To: Bahadori, Tina

Cc: Ramasamy, Santhini; Jones, Samantha; Lavoie, Emma; Ross, Mary; Hagerthey, Scot; Glenn, Barbara **Subject:** Fw: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Deliberative Process / Ex. 5

-Andrew

From: Kraft, Andrew

Sent: Friday, September 8, 2017 11:20 AM

To: Lidka Maslankiewicz

Cc: Els Smit; Paul Janssen; Joke Herremans; Glenn, Barbara; D'Amico, Louis; Bussard, David; Thayer, Kris **Subject:** Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hi Lidka,

Barbara (Glenn) and I are the current chemical managers of the formaldehyde assessment. We were hoping we might be able to set up a phone conversation to talk through the current status of the assessment and your questions below? If so, I can send out some type of Google poll or similar to find a time that works for everyone who might want to participate?

I would emphasize to you that the draft you mention was never finalized after it was released for the purposes of peer consultation and review. Thus, it should not be cited as an EPA position. We can explain this in greater detail when we talk.

We look forward to future conversations, Andrew and Barbara

From: Lidka Maslankiewicz < lidka.maslankiewicz@rivm.nl>

Sent: Tuesday, August 29, 2017 7:59 AM

To: Kraft, Andrew

Cc: Els Smit; Paul Janssen; Joke Herremans

Subject: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Dr Kraft,

My name is Lidka Maslankiewicz and I work at the Dutch National Institute for Public Health and the Environment (RIVM). We are currently busy with the update of the Maximum Permissible Risk (MPR) for formaldehyde.

We would like to use the approach and values described in IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010), in particular Volume 3: "Quantitative Assessment, Major Conclusions in the Characterization of Hazard and Dose Response"

(https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614), to derive MPR value for the Netherlands. Could you, please, inform me, if this could be permitted? Are there more recent versions of this document? If we would be allowed to use your data, how we could refer to the source?

IRIS Toxicological Review of Formaldehyde (Inhalation ...

cfpub.epa.gov

EPA announces the release of the Toxicological Review of Formaldehyde-Inhalation Assessment in the June 2, 2010 Federal Register Notice. This draft assessment is ...

Kind regards
Lidka
Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products
tel. 31 (0)30 2743160
+31 6 46 86 07 73
fax. 31 (0)30 2744401

e-mail: Lidka.Maslankiewicz@rivm.nl

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

www.rivm.ni De zorg voor morgen begint vandaag

Telephopeninthyle Telephon	on has work many, a debat help het de be.	est beautheliste.		

RIVM

www.rivm.nl

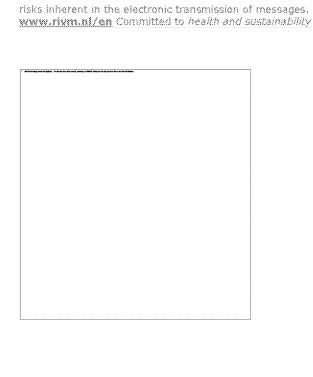
Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en wetenschappelijke onderbouwing van het volksgezondheidsbeleid. Ook valt het informatiecentrum ...

This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message. RIVM accepts no liability for damage of any kind resulting from the

chinosp bests hight. To bin a foreign concept that the site bin prior to contract the contract t	
	Rijksinstituut
	voor
	Volksgezondhei
	en Milieu - RIVM
	www.rivm.nl
	Dutch experts on
	climate change
	adaptation join forces. Fourteen Dutch
	knowledge institutes
	have joined forces to
	provide practical, demand-driven policy
	advice based
rzonden, wordt u verzocht dat aan de afzender te melden	d. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor
zonden, wordt u verzocht dat aan de afzender te melden iade, van welke aard ook, die verband houdt met risico's v	en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor verbonden aan het elektronisch verzenden van berichten.
zonden, wordt u verzocht dat aan de afzender te melden iade, van welke aard ook, die verband houdt met risico's v	en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor
zonden, wordt u verzocht dat aan de afzender te melden ade, van welke aard ook, die verband houdt met risico's v	en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor verbonden aan het elektronisch verzenden van berichten. RIVM
zonden, wordt u verzocht dat aan de afzender te melden ade, van welke aard ook, die verband houdt met risico's v	en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor verbonden aan het elektronisch verzenden van berichten. RIVM www.rivm.nl
zonden, wordt u verzocht dat aan de afzender te melden ade, van welke aard ook, die verband houdt met risico's v	en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor verbonden aan het elektronisch verzenden van berichten. RIVM www.rivm.nl Dit Nederlandse overheidsinstituut verzorgt informatie,
zonden, wordt u verzocht dat aan de afzender te melden iade, van welke aard ook, die verband houdt met risico's v	en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor verbonden aan het elektronisch verzenden van berichten. RIVM www.rivm.nl Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en
rzonden, wordt u verzocht dat aan de afzender te melden nade, van welke aard ook, die verband houdt met risico's v	en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor verbonden aan het elektronisch verzenden van berichten. RIVM www.rivm.nl Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en wetenschappelijke
rzonden, wordt u verzocht dat aan de afzender te melden nade, van welke aard ook, die verband houdt met risico's v	en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor verbonden aan het elektronisch verzenden van berichten. RIVM www.rivm.nl Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en wetenschappelijke onderbouwing van het volksgezondheidsbelei
	en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor verbonden aan het elektronisch verzenden van berichten. RIVM www.rivm.nl Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en wetenschappelijke onderbouwing van he

This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message. RIVM accepts no liability for damage of any kind resulting from the

risks inherent in the electronic transmission of messages.



Rijksinstituut voor Volksgezondheid en Milieu - RIVM

www.rivm.nl

Dutch experts on climate change adaptation join forces. Fourteen Dutch knowledge institutes have joined forces to provide practical, demand-driven policy advice based ...

Appointment

From: Fritz, Jason [Fritz.Jason@epa.gov]

Sent: 5/21/2015 3:58:57 PM

To: Gibbons, Catherine [Gibbons.Catherine@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara

[Glenn.Barbara@epa.gov]; Caldwell, Jane [Caldwell.Jane@epa.gov]; Sonawane, Bob [Sonawane.Bob@epa.gov];

Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Cogliano, Vincent [cogliano.vincent@epa.gov]

Subject: FA LHP MOA draft markup discussion; Personal Matters / Ex. 6 https://epa.connectsolutions.com/tpwg/

Attachments: Modes of action for Lymphoma revised draft 051515.docx; Appendix 1 lhp moa 051515.docx

Location: DCRoomPYN7771-North/ORD-NCEA-DC

Start: 5/28/2015 1:00:00 PM **End**: 5/28/2015 5:00:00 PM

Show Time As: Tentative

Hello everyone,

Deliberative Process / Ex. 5

To that end, everyone please read and become familiar with the revised draft synthesis section attached, prior to the meeting. This will be conducive to a good discussion and will facilitate stepping through important aspects of each section.



Modes of action for Lymphoma revis...

For reference, I am also attaching the Appendix which was provided by Jane to accompany this revised draft. This is FYI and may facilitate review/understanding of the MOA synthesis, but we will not be going over this section during the course of this markup meeting.



Appendix 1 lhp moa 051515.docx

Thanks, and we look forward to a constructive discussion next week! Jason Fritz, TPWG co-chair

Call-in and abode connect info:

Personal Matters / Ex. 6	
1 Crooner Meters / Ext C	

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]

Sent: 4/25/2016 9:15:01 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: FW: updated draft slides for Kavlock briefing

Attachments: Kavlock_Apr2016_bckgrnd.docx

From: Kraft, Andrew

Sent: Monday, April 25, 2016 5:09 PM

To: Bussard, David <Bussard.David@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; Perovich, Gina

<Perovich.Gina@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>

Cc: Glenn, Barbara <Glenn.Barbara@epa.gov>

Subject: RE: updated draft slides for Kavlock briefing

Thank you, David.

Please see the attached draft background materials for Bob K.

-Barbara and Andrew

From: Bussard, David

Sent: Monday, April 25, 2016 4:28 PM

To: Kraft, Andrew < Kraft. Andrew@epa.gov>; Birchfield, Norman < Birchfield. Norman@epa.gov>; Perovich, Gina

<Perovich.Gina@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>

Cc: Glenn, Barbara < <u>Glenn.Barbara@epa.gov</u>>

Subject: RE: updated draft slides for Kavlock briefing

Barbara and Andrew,

I like the revisions.

It is still potentially a lot to cover, but I think if you are clear what you want to cover if you are short on time and what you can cover if there is more time or Bob K wants to pursue a point, I think this can work.

David

From: Kraft, Andrew

Sent: Monday, April 25, 2016 4:12 PM

To: Bussard, David < Bussard. David @epa.gov >; Birchfield, Norman < Birchfield. Norman @epa.gov >; Perovich, Gina

<Perovich.Gina@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>

Cc: Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>

Subject: updated draft slides for Kavlock briefing

Hi all,

Please see the attached revised slide deck for the Kavlock briefing this Thursday and let us know if you have any comments.

Deliberative Process / Ex. 5

Thanks!

-Barbara and Andrew

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]

Sent: 3/9/2017 9:03:46 PM

To: Birchfield, Norman [Birchfield.Norman@epa.gov]

Subject: FW: Boomerang -- Letter Submitted on Behalf of the ACC Formaldehyde Panel Attachments: Letter to EPA NCEA Director on Formaldehyde IRIS - Final- 03 07 17.pdf

From: Bahadori, Tina

Sent: Thursday, March 09, 2017 4:23 AM

To: Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis

<DAmico.Louis@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Hagerthey,

Scot <Hagerthey.Scot@epa.gov>

Subject: Boomerang -- Letter Submitted on Behalf of the ACC Formaldehyde Panel

Dear Barbara and Andrew,

Deliberative Process / Ex. 5

Thanks, Tina

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Tuesday, March 7, 2017 8:16 AM

To: Bahadori, Tina < Bahadori, Tina@epa.gov >
Cc: Kavlock, Robert < Kavlock, Robert@epa.gov >

Subject: Letter Submitted on Behalf of the ACC Formaldehyde Panel

Dear Dr. Bahadori:

Please find attached a letter submitted on behalf of the American Chemistry Council Formaldehyde Panel.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

mericanchemistry.com		

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]

Sent: 12/22/2015 10:50:06 PM

To: Sonawane, Bob [sonawane.bob@epa.gov]; Bussard, David [bussard.david@epa.gov]
CC: Glenn, Barbara [glenn.barbara@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: Hazard Draft

Attachments: FormaldehydeTRdraft12215.docx; FormaldehydeAppendixdraft_122215.docx

Hi Bob and David,

Please find the attached (incomplete) hazard draft. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

in most

instances) we included it for your review anyway.

As this represents a work in progress, there are comment bubbles and formatting indications throughout.

I am also attaching a more preliminary draft of the Appendix materials, which is less ready for review.

Bob already has the most recent copy of the Response to Comments document, which we shared a week or two ago.

Enjoy! Happy holidays to you and your families, and see you next year (the latter from Andrew only, as Barbara will be here next week).

-Barbara and Andrew

From: Ravi S. [Ex. 6 - Personal Privacy 20 gmail.com]

Sent: 6/14/2018 2:47:03 AM

To: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]

Subject: files

Attachments: Formaldehyde Main Text 102417 06-13-18.docx; final edits main.docx

--Ravi.

From: Arzuaga, Xabier [Arzuaga.Xabier@epa.gov]

Sent: 7/9/2016 3:33:44 AM

To: Jones, Samantha [Jones.Samantha@epa.gov]

CC: Lee, Janice [Lee. JaniceS@epa.gov]; Hotchkiss, Andrew [Hotchkiss.Andrew@epa.gov]; Subramaniam, Ravi

[Subramaniam.Ravi@epa.gov]

Subject: Re: Formaldehyde review comments and discussion meeting

Attachments: Formaldehyde XA JL comments.docx; Formaldehyde_draft TR_ERC_May 2016_XA JL.pdf

Hello Samantha,

Thank you for the opportunity to review the draft IRIS Toxicological Review of Formaldehyde. Janice and I reviewed the MOA sections for non-cancer effects. Our comments are attached to this e-mail. Please let us know if you have any question. Have a nice weekend! Xabier

From: Jones, Samantha

Sent: Wednesday, June 29, 2016 5:19 PM

To: Gibbons, Catherine; Patel, Molini; Hazari, Mehdi; Lehmann, Geniece; Wright, Michael; Hotchkiss, Andrew; Walker,

Teneille; Arzuaga, Xabier; Lee, Janice; White, Paul; Kopylev, Leonid; Davis, Allen; Hogan, Karen; Jarabek, Annie Cc: Flowers, Lynn; Vandenberg, John; Cogliano, Vincent; Kraft, Andrew; Glenn, Barbara; Birchfield, Norman

Subject: Formaldehyde review comments and discussion meeting

Hi all,

First thank you all for agreeing to participate in this important review step for NCEA. It is greatly appreciated. For those of you in the "to" line in this email, you may recall that the deadline for comments is July 8th. I am in the process of scheduling a discussion meeting so that you all can walk through your major comments with the larger group and the assessment team. Given the number of sections and individual reviewers (see table below), I will likely schedule two meetings grouping reviewers/sections as appropriate. Be on the lookout for meeting invites in the near future.

Please note that prior to contacting each of you, we brought in three primary reviewers (Lynn Flowers, John Vandenberg, and Vince Cogliano) to review the overall assessment. We will be hosting a meeting for them to discuss their comments on Tuesday, July 12th from 9:00am to 10:30am. If you would like to sit in as an observer, please let me know.

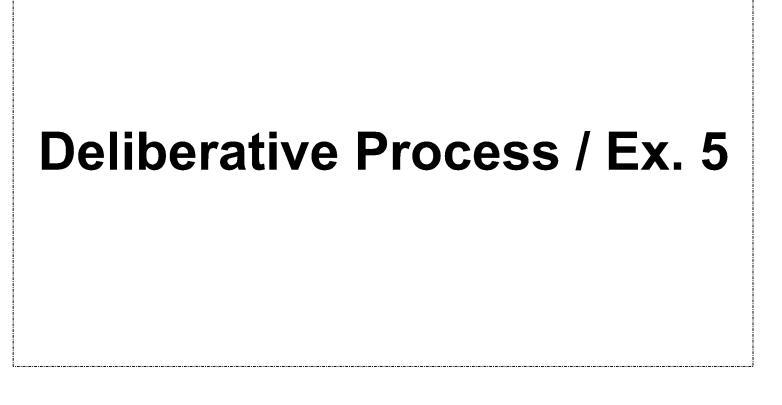
Thanks again for your commitment and assistance in moving this assessment forward!

Samantha

Samantha J. Jones, Ph.D Acting Associate Director for Health, ORD/NCEA

Phone: (703) 347-8580

Deliberative Process / Ex. 5



From: Jones, Samantha [Jones.Samantha@epa.gov]

Sent: 6/13/2016 2:44:52 PM

To: Walker, Teneille [Walker.Teneille@epa.gov]

CC: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]

Subject: Formaldehyde: NCEA Executive Review Committee

Attachments: Formaldehyde draft Appendices ERC May2016.docx; Formaldehyde draft Tox Review ERC May2016.docx;

Formaldehyde Issues raised for ERC Issues May2016.docx

Hi Teneille,

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Jithough the draft assessment (attached) does

not include a table of contents, you can go to the "View" table and select "Navigation Pane" and you can maneuver through the assessment that way.

The comment deadline is Friday, July 8th. We will have a meeting to discuss major issues/comments with the larger group soon after that.

Let me know if you have any concerns.

Thanks, Samantha

Samantha J. Jones, Ph.D Acting Associate Director for Health, ORD/NCEA Phone: (703) 347-8580

From: Jones, Samantha

Sent: Tuesday, May 24, 2016 8:28 PM

To: Olden, Kenneth < Olden.Kenneth@epa.gov>; Vandenberg, John < Vandenberg.John@epa.gov>; Lynn Flowers < Flowers.Lynn@epa.gov>; Cogliano, Vincent < Cogliano.vincent@epa.gov>; Perovich, Gina < Perovich.Gina@epa.gov>; Ross, Mary < Ross.Mary@epa.gov>; Walsh, Debra < Walsh.Debra@epa.gov>; Bussard, David < Bussard.David@epa.gov>; Hagerthey, Scot < Hagerthey, Scot @epa.gov>; Birchfield, Norman < Birchfield.Norman@epa.gov>; Morozov, Viktor < Morozov, Viktor@epa.gov>; Susan Rieth < Rieth.Susan@epa.gov>; Andrew Hotchkiss < Hotchkiss.Andrew@epa.gov>; Subramaniam, Ravi < subramaniam.ravi@epa.gov>; Stanek, John < Stanek.John@epa.gov>; Lambert, Jason < Lambert.Jason@epa.gov>; Hawkins, Belinda < Hawkins.Belinda@epa.gov>; Johnson, Craig < Johnson.Craig@epa.gov>; Gatchett, Annette < Gatchett.Annette@epa.gov>; Ted Berner < Berner.Ted@epa.gov>; D'Amico, Louis < damico.louis@epa.gov>; Glenn, Barbara < Glenn.Barbara@epa.gov>; Kraft, Andrew < Kraft.Andrew@epa.gov>; White, Paul < White.Paul@epa.gov>

Subject: Formaldehyde: ERC Review

Hello all,

Deliberative Process / Ex. 5

Attached are clean drafts of the toxicological review and supplemental information (i.e., appendices). Please note that these documents have not yet undergone tech edit, and all of the callouts to tables, figures, and other sections are not included. Additionally, while these documents are clean (i.e., no track changes), there are a few comment bubbles

remaining to note some items the team is still working to address. The other attachment details several topics raised for ERC review; these are briefly highlighted below. **Comments are due by June 22nd**; please cc' all on this email with comments. An ERC meeting will be scheduled for shortly after the 22nd.

Highlighted topics covering assessment approaches for ERC reviewers to consider

Deliberative Process / Ex. 5

Thanks, Samantha

Samantha J. Jones, Ph.D Acting Associate Director for Health, ORD/NCEA Phone: (703) 347-8580 From: Jones, Samantha [Jones.Samantha@epa.gov]

Sent: 6/13/2016 2:12:52 PM

To: Arzuaga, Xabier [Arzuaga.Xabier@epa.gov]

CC: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]

Subject: Formaldehyde: NCEA Executive Review Committee

Attachments: Formaldehyde draft Appendices ERC May2016.docx; Formaldehyde draft Tox Review ERC May2016.docx;

Formaldehyde Issues raised for ERC Issues May2016.docx

Hi Xabier,

Deliberative Process / Ex. 5

The comment deadline is Friday, July 8th. We will have a meeting to discuss major issues/comments with the larger group soon after that.

Let me know if you have any concerns.

Thanks, Samantha

Samantha J. Jones, Ph.D Acting Associate Director for Health, ORD/NCEA Phone: (703) 347-8580

From: Jones, Samantha

Sent: Tuesday, May 24, 2016 8:28 PM

To: Olden, Kenneth < Olden.Kenneth@epa.gov>; Vandenberg, John < Vandenberg.John@epa.gov>; Lynn Flowers < Flowers.Lynn@epa.gov>; Cogliano, Vincent < Cogliano.vincent@epa.gov>; Perovich, Gina < Cogliano.vincent@epa.gov>; Perovich, Gina < Cogliano.vincent@epa.gov>; Perovich, Gina < Cogliano.vincent@epa.gov>; Perovich, Gina < Cogliano.vincent@epa.gov>; Bussard, David < Cogliano.vincent@epa.gov>; Morozov, Viktor < Cogliano.vincent@epa.gov>; Morozov, Viktor < Cogliano.vincent@epa.gov>; Andrew Hotchkiss < Cogliano.vincent@epa.gov>; Andrew Hotchkiss < Cogliano.vincent@epa.gov>; Stanek, John < Cogliano.vincent@epa.gov>; Lambert, Jason < Cogliano.vincent@epa.gov>; Stanek, John < Cogliano.vincent@epa.gov>; Johnson, Craig < Cogliano.vincent@epa.gov>; Gatchett, Annette@epa.gov>; Ted Berner < Cogliano.vincent@epa.gov>; D'Amico, Louis < Cogliano.vincent@epa.gov>; White, Paul < White.Paul@epa.gov>; White, Paul < White.Paul@epa.gov>

Subject: Formaldehyde: ERC Review

Hello all,

Deliberative Process / Ex. 5

Attached are clean drafts of the toxicological review and supplemental information (i.e., appendices). Please note that these documents have not yet undergone tech edit, and all of the callouts to tables, figures, and other sections are not included. Additionally, while these documents are clean (i.e., no track changes), there are a few comment bubbles remaining to note some items the team is still working to address. The other attachment details several topics raised for

ERC review; these are briefly highlighted below. **Comments are due by June 22nd**; please cc' all on this email with comments. An ERC meeting will be scheduled for shortly after the 22nd.

Highlighted topics covering assessment approaches for ERC reviewers to consider

Deliberative Process / Ex. 5

Thanks, Samantha

Samantha J. Jones, Ph.D Acting Associate Director for Health, ORD/NCEA Phone: (703) 347-8580 From: Jones, Samantha [Jones.Samantha@epa.gov]

Sent: 5/25/2016 12:59:04 AM

To: Newhouse, Kathleen [Newhouse.Kathleen@epa.gov]
CC: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]
Subject: Formaldehyde: NCEA Executive Review Committee

Attachments: Formaldehyde draft Appendices ERC May2016.docx; Formaldehyde draft Tox Review ERC May2016.docx;

Formaldehyde_Issues raised for ERC Issues_May2016.docx

Hi Kathleen,

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

we are asking you to set aside some time to

conduct this review. Let me know if you have any concerns.

Thanks, Samantha

Samantha J. Jones, Ph.D Acting Associate Director for Health, ORD/NCEA

Phone: (703) 347-8580

From: Jones, Samantha

Sent: Tuesday, May 24, 2016 8:28 PM

To: Olden, Kenneth <<u>Olden.Kenneth@epa.gov</u>>; Vandenberg, John <<u>Vandenberg.John@epa.gov</u>>; Lynn Flowers <<u>Flowers.Lynn@epa.gov</u>>; Cogliano, Vincent <<u>cogliano.vincent@epa.gov</u>>; Perovich, Gina <<u>Perovich.Gina@epa.gov</u>>; Ross, Mary <<u>Ross.Mary@epa.gov</u>>; Walsh, Debra <<u>Walsh.Debra@epa.gov</u>>; Bussard, David <<u>Bussard.David@epa.gov</u>>; Hagerthey, Scot <<u>Hagerthey.Scot@epa.gov</u>>; Birchfield, Norman <<u>Birchfield.Norman@epa.gov</u>>; Morozov, Viktor <<u>Morozov.Viktor@epa.gov</u>>; Susan Rieth <<u>Rieth.Susan@epa.gov</u>>; Andrew Hotchkiss <<u>Hotchkiss.Andrew@epa.gov</u>>; Subramaniam, Ravi <<u>subramaniam.ravi@epa.gov</u>>; Stanek, John <<u>Stanek.John@epa.gov</u>>; Lambert, Jason <<u>Lambert.Jason@epa.gov</u>>; Hawkins, Belinda <<u>Hawkins.Belinda@epa.gov</u>>; Johnson, Craig <<u>Johnson.Craig@epa.gov</u>>; Gatchett, Annette <<u>Gatchett.Annette@epa.gov</u>>; Ted Berner <<u>Berner.Ted@epa.gov</u>>; D'Amico, Louis <<u>damico.louis@epa.gov</u>>; Glenn, Barbara <<u>Glenn.Barbara@epa.gov</u>>; Kraft, Andrew <<u>Kraft.Andrew@epa.gov</u>>; White, Paul <<u>White.Paul@epa.gov</u>>

Subject: Formaldehyde: ERC Review

Hello all,

Deliberative Process / Ex. 5

ttached are clean drafts of the toxicological review and supplemental information (i.e., appendices). Please note that these documents have not yet undergone tech edit, and all of the callouts to tables, figures, and other sections are not included. Additionally, while these documents are clean (i.e., no track changes), there are a few comment bubbles remaining to note some items the team is still working to address. The other attachment details several topics raised for ERC review; these are briefly highlighted below. **Comments are due by June 22nd**; please cc' all on this email with comments. An ERC meeting will be scheduled for shortly after the 22nd.

Highlighted topics covering assessment approaches for ERC reviewers to consider

Deliberative Process / Ex. 5

Thanks, Samantha

Samantha J. Jones, Ph.D Acting Associate Director for Health, ORD/NCEA Phone: (703) 347-8580

From: Ravi S. Ex. 6 - Personal Privacy [9gmail.com]

Sent: 1/11/2017 3:13:39 AM

To: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]

Subject: files 1-10-17 pm

Attachments: bussard-Vince comments.01-08-17.docx; Main SCC d-r- 1-8-17.docx

--Ravi.

Ravi S. Ex. 6 - Personal Privacy @gmail.com] From:

Sent: 1/9/2017 2:21:37 AM

Ravi Subramaniam [Ex. 6 - Personal Privacy pgmail.com]; Subramaniam, Ravi [Subramaniam.Ravi@epa.gov] To:

Subject: files pm

Attachments: Main SCC d-r- 1-4-17.docx; bussard-Vince comments.01-05-17.docx

--Ravi.

From: Arzuaga, Xabier [Arzuaga.Xabier@epa.gov]

Sent: 6/23/2016 7:39:11 PM

To: Lee, Janice [Lee.JaniceS@epa.gov]

CC: Hotchkiss, Andrew [Hotchkiss.Andrew@epa.gov]; Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]

Subject: RE: Formaldehyde review

Attachments: Formaldehyde draft TR ERC May 2016 XA JL.pdf; Formaldehyde XA comments.docx

Hi Janice,
| hope you are enjoying the meeting and that your talk goes well.
| Deliberative Process / Ex. 5 | am attaching my notes to this e-mail. Please let me know when it would be most convenient for you to meet and discuss our review and next steps. Cheers!

Xabier

From: Arzuaga, Xabier

Sent: Monday, June 20, 2016 3:48 PM **To:** Lee, Janice <Lee.JaniceS@epa.gov>

Cc: Hotchkiss, Andrew < Hotchkiss. Andrew@epa.gov >; Subramaniam, Ravi < Subramaniam. Ravi@epa.gov >

Subject: Formaldehyde review

Hi Janice,

Deliberative Process / Ex. 5

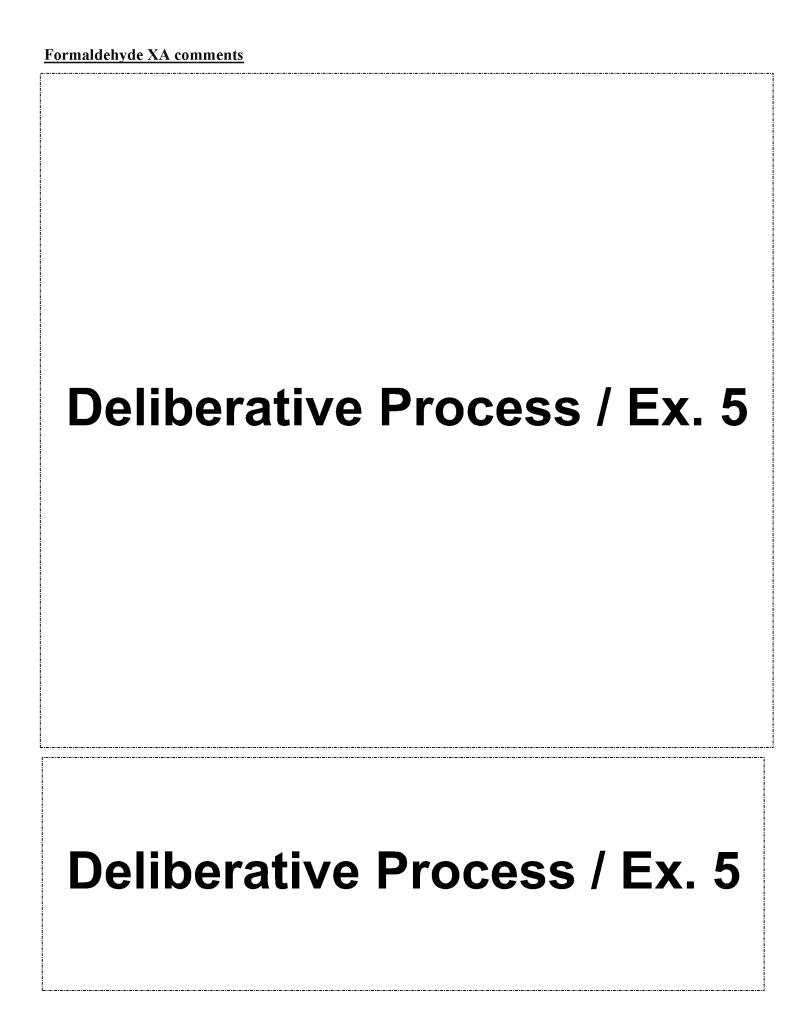
Deliberative Process / Ex. 5

Most of my

comments are on minor changes. One issue that I am finding is that the authors of this section did not cite much and it is difficult to find which study reported what on the tables. I hope to finish by tomorrow or Wednesday. Thanks!

Xabier

Deliberative Process / Ex. 5



Deliberative Process / Ex. 5
Deliberative Process / Ex. 5

From: Subramaniam, Ravi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E738F9D27062486E9047184B867FD968-SUBRAMANIAM, RAVI]

Sent: 1/4/2017 8:51:48 PM

To: Ravi S. Ex. 6 - Personal Privacy pgmail.com]

Subject: formaldehyde

Attachments: Main SCC d-r- 1-4-17.docx; Human Model Report_3.doc

--Ravi.

Ravi Subramaniam, PhD / Chief, Toxic Effects Branch-IRIS, NCEA-ORD, EPA. Room PYS-11782/ Ph: (703) 347-8606 (o); (571) 305-3601 (m)

Kraft, Andrew [Kraft.Andrew@epa.gov] From:

11/30/2017 2:33:10 PM Sent:

To: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]; Bussard, David [Bussard.David@epa.gov]

CC: Glenn, Barbara [Glenn.Barbara@epa.gov]; Ramasamy, Santhini [Ramasamy.Santhini@epa.gov]; Vulimiri,

Suryanarayana [Vulimiri.Sury@epa.gov]

Subject: RE: Hot off the press on Endogenous Formaldehyde

Attachments: formaldehyde_assessment overview_IOAAreview_102617rssvedits.docx; Formaldehyde Main Text

102417rssvEdits.docx

Hi Ravi, good question. It is just too problematic at this point for you to be working in the master versions (on Sharepoint) that Barbara and I are working on.

So, I have attached here a current copy of the main draft and overview documents. Please crosswalk any changes across both documents, and let us know if you also need to make changes to the Appendices (which you can probably work on directly in Sharepoint, as we are not yet working on them).

Since it sounds like you will be working on making changes before Sury, we would prefer if you could make your edits in track changes and then send the docs to Sury, who can then send the docs back to us (or something similar).

Thanks!

From: Subramaniam, Ravi

Sent: Thursday, November 30, 2017 9:09 AM

To: Kraft, Andrew < Kraft. Andrew@epa.gov >; Bussard, David < Bussard. David@epa.gov >

Cc: Glenn, Barbara <Glenn.Barbara@epa.gov>; Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>; Vulimiri,

Suryanarayana < Vulimiri. Sury@epa.gov>

Subject: RE: Hot off the press on Endogenous Formaldehyde

I have set aside some time this morning for formaldehyde, and will add this to my agenda. However, Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process Someone else, Sury perhaps?, needs to add, if necessary, elsewhere.

Andrew,	how should I do this	(and the other edits	I have promised)?	Directly, or send	you the blurb s	eparately?
-						
Ravi.						

Ravi Subramaniam

RRB 51237/ (202) 564-2445 (o), (571) 305-3601 (m)

From: Kraft, Andrew

Sent: Thursday, November 30, 2017 7:56 AM

To: Subramaniam, Ravi < Subramaniam.Ravi@epa.gov >; Bussard, David < Bussard.David@epa.gov >

Cc: Glenn, Barbara < Glenn.Barbara@epa.gov>; Ramasamy, Santhini < Ramasamy.Santhini@epa.gov>; Vulimiri,

Suryanarayana < Vulimiri. Sury@epa.gov>

Subject: RE: Hot off the press on Endogenous Formaldehyde

Ex. 5 - Deliberative Process

Thanks for sharing, Sury!

From: Subramaniam, Ravi

Sent: Thursday, November 30, 2017 7:26 AM **To:** Bussard, David < <u>Bussard</u>. <u>David@epa.gov</u>>

Cc: Kraft, Andrew < Kraft. Andrew@epa.gov >; Glenn, Barbara < Glenn. Barbara@epa.gov >; Ramasamy, Santhini

<Ramasamy.Santhini@epa.gov>

Subject: Re: Hot off the press on Endogenous Formaldehyde

Yes. We have made this point that Sury makes that

When our repair systems don't work for some reason, any endogenous chemical can cause a risk, but the reference and elaboration he gives would help buttress the point. Good!

--Ravi.

Ravi Subramaniam, Ph.D.

Chief, Toxic Effects Branch, IRIS, NCEA, EPA

RRB 51237/ (202) 564-2445 (O) / (571) 305-3601 (m)

On Nov 30, 2017, at 7:04 AM, Bussard, David < Bussard. David@epa.gov > wrote:

Ravi

This new work -

Ex. 5 - Deliberative Process

David Bussard

Begin forwarded message:

From: "Vulimiri, Suryanarayana" < <u>Vulimiri.Sury@epa.gov</u>>

Date: November 29, 2017 at 5:39:41 PM EST

To: "Bussard, David" <Bussard.David@epa.gov>

Subject: RE: Hot off the press on Endogenous Formaldehyde

David, that is the question I have. It needs some collective thinking into it. Here are some preliminary thoughts.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Sury

Sury Vulimiri, Ph.D., DABT National Center for Environmental Assessment, Office of Research & Development, US EPA. Phone: 919-541-3558 | Fax: 919-541-0245 | vulimiri.sury@epa.gov

From: Bussard, David

Sent: Wednesday, November 29, 2017 5:06 PM **To:** Vulimiri, Suryanarayana < <u>Vulimiri.Sury@epa.gov</u>>

Subject: RE: Hot off the press on Endogenous Formaldehyde

Thanks Sury

What do you think this means for the role of endogenous formaldehyde in assessing the risk of inhaled formaldehyde?

David

From: Vulimiri, Suryanarayana

Sent: Wednesday, November 29, 2017 4:43 PM

To: Bateson, Thomas < Bateson. Thomas@epa.gov>; Glenn, Barbara

<Glenn.Barbara@epa.gov>; Fritz, Jason <Fritz.Jason@epa.gov>; Kraft, Andrew

< Kraft.Andrew@epa.gov>; Makris, Susan Makris, Susan@epa.gov>; Segal, Deborah

<Segal.Deborah@epa.gov>; Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>;

Vulimiri, Suryanarayana < Vulimiri.Sury@epa.gov; Whalan, John

<Whalan.John@epa.gov>

Cc: Bussard, David < Bussard. David@epa.gov >; Ramasamy, Santhini

<Ramasamy.Santhini@epa.gov>

Subject: Hot off the press on Endogenous Formaldehyde

Nature, 2017 Aug 31;548(7669):549-554. doi: 10.1038/nature23481. Epub 2017 Aug 16.

Mammals divert endogenous genotoxic formaldehyde into one-carbon metabolism.

Burgos-Barragan G¹, Wit N¹, Meiser J², Dingler FA¹, Pietzke M², Mulderrig L¹, Pontel LB¹, Rosado IV², Brewer TF², Cordell RL², Monks PS², Chang CJ², Vazquez A², Patel KJ².

Author information

1

MRC Laboratory of Molecular Biology, Francis Crick Avenue, Cambridge CB2 0QH, UK.

2

Cancer Research UK Beatson Institute, Glasgow G61 1BD, UK.

3

Instituto de Biomedicina de Sevilla (IBiS) Hospital Universitario Virgen del Rocío/CSIC/Universidad de Sevilla, 41013 Seville, Spain.

4

Department of Chemistry, Department of Molecular and Cell Biology, and Howard Hughes Medical Institute, University of California, Berkeley, Berkeley, California 94720, USA.

5

Department of Chemistry, University of Leicester, Leicester LE1 7RH, UK.

6

University of Cambridge, Department of Medicine, Addenbrooke's Hospital, Cambridge CB2 2QQ, UK.

Abstract

The folate-driven one-carbon (1C) cycle is a fundamental metabolic hub in cells that enables the synthesis of nucleotides and amino acids and epigenetic modifications. This cycle might also release formaldehyde, a potent protein and DNA crosslinking agent that organisms produce in substantial quantities. Here we show that supplementation with tetrahydrofolate, the essential cofactor of this cycle, and other oxidation-prone folate derivatives kills human, mouse and chicken cells that cannot detoxify formaldehyde or that lack DNA crosslink repair. Notably, formaldehyde is generated from oxidative decomposition of the folate backbone. Furthermore, we find that formaldehyde detoxification in human cells generates formate, and thereby promotes nucleotide synthesis. This supply of 1C units is sufficient to sustain the growth of cells that are unable to use serine, which is the predominant source of 1C units. These findings identify an unexpected source of formaldehyde and, more generally, indicate that the detoxification of this ubiquitous endogenous genotoxin creates a benign 1C unit that can sustain essential metabolism.

PMID: 28813411 DOI:

10.1038/nature23481

<< File: Burgos-Barragan et al 2017_EndogenouFA.pdf >> << File: Pontel et al 2015 SV.pdf >>

So the bottom line is that endogenous formaldehyde is safely handled by the cells diverting it into normal cellular metabolism. This is published in Nature (PDF attached).

Ex. 5 - Deliberative Process

One of the co-authors is Pontel, who published earlier an article titled "Endogenous formaldehyde is a hematopoietic stem cell genotoxin and metabolic carcinogen" in the Journal 'Molecular Cell' on which Dr. Swenberg is a co-author.

Sury

Sury Vulimiri, Ph.D., DABT National Center for Environmental Assessment, Office of Research & Development, US EPA. Phone: 919-541-3558 | Fax: 919-541-0245 | vulimiri.sury@epa.gov

From: Sonawane, Bob [Sonawane.Bob@epa.gov]

Sent: 1/4/2016 8:13:37 PM

To: Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]

Subject: FW: Hazard Draft

Attachments: FormaldehydeTRdraft12215.docx; FormaldehydeAppendixdraft_122215.docx

From: Kraft, Andrew

Sent: Tuesday, December 22, 2015 5:50 PM

To: Sonawane, Bob <Sonawane.Bob@epa.gov>; Bussard, David <Bussard.David@epa.gov> **Cc:** Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>

Subject: Hazard Draft

Hi Bob and David,

Please find the attached (incomplete) hazard draft.	ii				
Ex. 5 - Deliberative Process					
	erative Process (in mos	st .			
incton and) was included it for your review anymou					

instances) we included it for your review anyway.

As this represents a work in progress, there are comment bubbles and formatting indications throughout.

I am also attaching a more preliminary draft of the Appendix materials, which is less ready for review.

Bob already has the most recent copy of the Response to Comments document, which we shared a week or two ago.

Enjoy! Happy holidays to you and your families, and see you next year (the latter from Andrew only, as Barbara will be here next week).

-Barbara and Andrew